

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CIVIL ACTION NO 16-MD-2738 (FLW) (LHG)

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IN RE JOHNSON & JOHNSON : DAUBERT HEARING
POWDER PRODUCTS MARKETING, : JULY 25, 2019
SALES PRACTICES. : VOLUME 4
----- :

CLARKSON S. FISHER UNITED STATES COURTHOUSE
402 EAST STATE STREET, TRENTON, NJ 08608

B E F O R E: THE HONORABLE FRED A. WOLFSON, USDJ

A P P E A R A N C E S:

BEASLEY ALLEN, ESQUIRES

BY: P. LEIGH O'DELL, ESQUIRE (ALABAMA)

-and-

ASHCRAFT & GEREL, ESQUIRES

BY: MICHELLE A. PARFITT, ESQUIRE (VIRGINIA)

-and-

LEVIN PAPANTONIO, ESQUIRES

BY: CHRISTOPHER V. TISI, ESQUIRE (FLORIDA)

-and-

ROBINSON CALCAGNIE, ESQUIRES

BY: CYNTHIA L. GARBER, ESQUIRE (CALIFORNIA)

behalf of the Plaintiffs Steering Committee

DRINKER, BIDDLE & REATH, ESQUIRES

BY: SUSAN M. SHARKO, ESQUIRE (NEW JERSEY)

JULIE L. TERSIGNI, ESQUIRE (NEW JERSEY)

-and-

SKADDEN, ARPS, SLATE, MEAGHER & FLOM, ESQUIRES

BY: JOHN H. BEISNER, ESQUIRE (WASHINGTON, D.C.)

-and-

PROSKAUER ROSE, ESQUIRES

BY: BART H. WILLIAMS, ESQUIRE (CALIFORNIA)

On behalf of Defendant Johnson & Johnson

(Continued)

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On behalf of Defendant Johnson & Johnson

SEYFARRTH & SHAW, ESQUIRES
BY: THOMAS L. LOCKE, ESQUIRE (WASHINGTON D.C.)
On Behalf of Defendant Personal Care Products Council

1 M O R N I N G S E S S I O N

2

3 (In open court.)

4 THE DEPUTY CLERK: All rise.

5 THE COURT: Thank you. Everyone may be
6 seated.

7 MS. PARFITT: At this time Plaintiffs will
8 call Dr. Anne McTiernan.

9

10 **ANNE MC TIERNAN**, called as a witness on behalf of
11 the Plaintiffs, having been first duly sworn,
12 testified as follows:

13

14 DIRECT EXAMINATION

15 BY MS. PARFITT:

16 Q. Dr. McTiernan, good morning.

17 A. Good morning.

18 Q. Would you please introduce yourself to the
19 Court.

20 A. Good morning, your Honor. My name is Dr. Anne
21 McTiernan.

22 Q. Dr. McTiernan, have you brought with you today,
23 for purposes of assisting you with the opinions you
24 will be sharing with her Honor your expert report and
25 your curriculum vitae and addendum tables?

1 A. Yes.

2 Q. Have you also brought with you a binder of
3 materials that consist of the relevant literature you
4 may be discussing this morning with the Court?

5 A. Yes.

6 Q. Finally, in preparation for your testimony
7 today, did you assist me in preparing some slides that
8 we can focus on today?

9 A. Yes.

10 Q. We will be showing those throughout the course
11 of the morning.

12 Dr. McTiernan, would you share with us what
13 your profession and field of expertise is.

14 A. I'm an epidemiologist, and I specialize in
15 women's health and cancer epidemiology.

16 Q. We need to hear what epidemiology is, and
17 frankly why the field of epidemiology is important for
18 the discussion this morning of ovarian cancer and
19 talcum powder.

20 A. Epidemiology is the study of disease in humans,
21 disease and risks. In epidemiology, we can determine
22 what are the associations between an exposure and risk
23 of disease. This is critical for this issue of talcum
24 powder products use in ovarian cancer because we don't
25 have clinical trial evidence. Studies in humans we're

1 really relying on epidemiology.

2 Q. You may move just a little bit closer to the
3 mic. Thank you.

4 Dr. McTiernan, if you will, summarize for the
5 Court -- and we will put a slide up here -- your
6 qualifications and expertise to prepare you to offer
7 the opinions you will be giving in this case.

8 A. In 1982 I completed a Ph.D. in epidemiology at
9 the University of Washington in Seattle, and I focused
10 on cancer epidemiology.

11 In 1989, I completed my medical degree at New
12 York Medical College. And then I moved to Seattle and
13 completed a residency in internal medicine at the
14 University of Washington in 1992.

15 Q. If you will -- we will move to the next slide --
16 briefly summarize for the Court the qualifications and
17 expertise with regard to academic appointments and
18 research.

19 A. Sure.

20 I am a full member at the Fred Hutchinson
21 Cancer Research Center in Seattle. This is a premier
22 independent cancer research center that first
23 identified bone marrow transplant, and it was the
24 first cancer prevention center in the country. There
25 I study ways to prevent new and recurrent cancer. I

1 conduct epidemiologic research, identify risk factors
2 for women such as breast and ovarian cancer, and I
3 study prevention methods to reduce population and
4 other markers of cancer risk.

5 I am also a research professor at the
6 University of Washington Schools of Medicine And
7 Public Health, and my departments there are
8 epidemiology and gerontology and geriatric medicine.
9 There I teach and mentor epidemiology students,
10 especially graduate students.

11 Q. What other research activities are you involved
12 in?

13 A. One key one is the Women's Health Initiative.
14 When I began at Fred Hutchinson in 1992, I was hired
15 to be a project director for the Women's Health
16 Initiative. This includes a cohort study that we will
17 be talking about later.

18 Q. If I can ask a question here. You are speaking
19 of the Women's Health Initiative also the Houghton
20 Study?

21 A. That's correct.

22 Q. You were project director?

23 A. Yes.

24 Q. Please.

25 A. There I've led the development of protocols

1 procedures, recruitment interventions because we had
2 trials as well, follow-up and outcomes including
3 ovarian cancer.

4 In terms of published research, I have
5 published over 400 scientific manuscripts and
6 peer-reviewed medical and scientific journals.

7 We put up here numbers of different types of
8 studies we will be talking about later that I've
9 published. I've published 17 case-control studies,
10 127 cohort studies, 165 randomized clinical trials,
11 ten pooled analyses, five methods, multiple meta-
12 analyses and multiple reviews.

13 Q. Thank you. We will be speaking about many of
14 those a bit later.

15 Now, will you briefly discuss with us
16 positions where you are in an advisory or consultancy
17 position for either a national or international
18 research organization?

19 A. Sure. Two relevant ones are for the World
20 Health Organization. They are the International
21 Agency for research on cancer. This is the cancer
22 branch of the World Health Organization.

23 In 2002 I was a member of a working group that
24 completed a systematic review and produced a handbook
25 of cancer prevention. That one was focused on

1 physical activity and weight control. There I chaired
2 a section to identify biologically plausible
3 mechanisms linking physical activity and weight to
4 cancer.

5 Q. Now, if you will, in the interest of time, just
6 briefly share with us as well what your work has been
7 with the World Cancer and other groups.

8 A. The World Cancer Research Fund, I'm a member of
9 the Continuous Update Panel that conducts research on
10 cancer prevention and survivorship, and this is
11 focused on diet, nutrition, physical activity, and
12 obesity.

13 Q. The work you do for the World Cancer Research
14 Fund is just focused on certain research areas?

15 A. That's correct, diet, nutrition, physical
16 activity and obesity.

17 Q. Please, if you will.

18 A. I also advised for the U.S. Government, which
19 includes advisory for the U.S. Department of Health
20 and Human Services advisory committees on physical
21 activity guidelines in 2008 and 2018, and there I was
22 chair of the cancer subcommittee.

23 I have been principal investigator of multiple
24 NCI grants, including the Seattle Transdisciplinary
25 Research on energetics and cancer.

1 I have been a program reviewer for NCI
2 research and reviewed grant applications.

3 I have also reviewed grant applications for
4 the Department of Defense.

5 Q. Dr. McTiernan, you spoke briefly about the
6 numerous almost 400 publications that you have
7 prepared over the course of your career. Do you also
8 act as a peer reviewer?

9 A. Yes. For many medical and scientific journals.
10 It has been an ongoing work that I do.

11 MS. PARFITT: Your Honor has your resume. We
12 are going to move forward and address some of the
13 other issues, if I may.

14 THE WITNESS: Okay.

15 Q. Dr. McTiernan, what was the issue you were asked
16 to review in this case?

17 A. So I was retained to review the current state of
18 the scientific literature regarding talcum powder
19 products and to opine on whether these products cause
20 ovarian cancer.

21 Q. Have you formulated an opinion regarding the
22 association between talcum powder products and ovarian
23 cancer, and are you prepared today to share your
24 methodology for developing those opinions?

25 A. Yes.

1 Q. What are those opinions?

2 A. My opinion as an epidemiologist and physician,
3 stated to a reasonable degree of medical and
4 scientific certainty, that use of talcum powder
5 products, including Johnson & Johnson Baby Powder and
6 Shower To Shower, in the genital perineal area can
7 cause ovarian cancer. I base this opinion on the
8 statistically significant elevated risk seen with the
9 epidemiology data when they are combined, the
10 pathological evidence, the consistency of results
11 across geographic areas, and in different race and
12 ethnic groups, evidence of a positive dose-response
13 effect, and the plausible biological mechanism.

14 Q. Dr. McTiernan, have you ever testified in a
15 court of law as an expert witness?

16 A. No, I have not.

17 Q. This is your first time in almost forty years of
18 a practicing epidemiologist that you have had the
19 pleasure of sitting up there and being quizzed. Is
20 that correct?

21 A. Yes.

22 Q. Dr. McTiernan, why did you decide to be an
23 expert witness in this case?

24 A. First I thought it would be an important issue
25 in women's health and public health. Second, I wanted

1 to share my scientific skills and expertise on this
2 issue.

3 Q. Now, in addition to your opinions you have set
4 forth in this litigation as an expert, have you shared
5 your opinions outside of this litigation?

6 A. Yes, I have.

7 Q. To whom have you shared your opinions?

8 A. There are two major areas where I have shared
9 publicly. The first is with Health Canada. Health
10 Canada prepared and released a document publicly and
11 that stated that the meta-analyses of available human
12 study in the peer-reviewed literature indicated
13 consistent and statistically significant positive
14 association between perineal exposure to talc and
15 ovarian cancer, and they stated further that available
16 data are indicative of a causal effect. This
17 conclusion agrees with my own, and that's what I
18 stated to them in public commentary.

19 Q. We'll get to the public commentary in just one
20 moment.

21 A couple of questions. To your understanding,
22 were there any dissimilarities between your
23 conclusions or your findings and that of Health
24 Canada?

25 A. They were quite similar. One difference is they

1 made the assumption there was no asbestos in the
2 talcum powder products.

3 Q. For purposes of your opinions that you are
4 sharing not only with the Court but the Health Canada
5 and Congress, you understand there is a presence of
6 asbestos as well?

7 A. Yes.

8 Q. Did you both do a systematic review?

9 A. I did.

10 Q. Did you both do a Bradford Hill causality
11 analysis?

12 A. Yes.

13 Q. You started to mention about a commentary. Were
14 you provided an opportunity, after your read of the
15 Health Canada assessment, to provide your remarks to
16 Health Canada or your opinions to Health Canada?

17 A. Yes.

18 Q. You did that?

19 A. Yes.

20 Q. Why don't you tell us when and what you did.

21 A. So in February of 2019, I submitted comments to
22 their website. They invited public commentary.

23 Q. What is it that you shared with Health Canada?

24 A. I stated their conclusion agreed with mine. I
25 told them how many publications I had reviewed, and

1 including pooled and meta-analyses, and I stated the
2 meta-analysis consistently showed that women who had
3 ever used talcum powder products in the genital area
4 had a statistically significant 22 to 31 percent
5 increased risk of developing epithelial ovarian cancer
6 overall, compared with women who had never used these
7 products. I stated that the comprehensive combined
8 analyses also showed strong evidence of increased risk
9 of ovarian cancer with increasing number of lifetime
10 applications of these products in the perineal/genital
11 area.

12 Q. After you submitted your comments, Dr.
13 McTiernan, what, if any, response did you receive from
14 Health Canada?

15 A. The next slide shows their acting senior manager
16 contacted me and asked if I would be willing to offer
17 my scientific opinion and my expertise to help them as
18 they conclude their project.

19 Q. Dr. McTiernan, after you made your comments
20 public to Health Canada and received a response by the
21 authorities at Health Canada requesting your expertise
22 in the future, did you have an opportunity to share
23 the opinions you are expressing today in the courtroom
24 with anyone else? I believe you mentioned Congress?

25 A. Yes, I did.

1 Q. Tell us about that.

2 A. I gave testimony to the U.S. Congress, to their
3 Committee on Oversight and Reform, Subcommittee on
4 Economic and Consumer Policy.

5 Q. And, specifically, how did that come to be?
6 What were you asked to do so you knew what your
7 responsibility or role would be before Congress?

8 A. One week before this meeting I was contacted by
9 the Committee and asked to provide my comments on the
10 association between talcum powder product use and risk
11 of ovarian cancer.

12 Q. And did you have to submit that public comment?

13 A. I did. I had a prepared five minutes of the
14 comments, and I also had the opportunity to submit a
15 document, and those are public.

16 Q. What I would like you to do is share with Her
17 Honor what your comments were to Congress with regard
18 to your opinions with regard to genital use of talcum
19 powder and causing ovarian cancer. What did you tell
20 Congress?

21 A. I told them how many studies I had reviewed. I
22 told them that summarizing the data across those
23 studies consistently showed women who had ever used
24 these products in the genital area had a statistically
25 significant 22 to 31 percent increased risk of

1 developing epithelial ovarian cancer compared with
2 women who never used them.

3 I further talked about the combined analysis
4 that showed increasing amount of exposure to these
5 products, increased risk of developing ovarian cancer
6 further, and this is dose-response. We'll talk more
7 about that later.

8 Q. Next slide.

9 What else did you share with Congress?

10 A. I further talked about biologically plausible
11 pathways through which these products can be causing
12 ovarian cancer and a particular focus on inflammatory
13 response that is caused by talc.

14 Also I talked about, given the frequency with
15 which asbestos has been found in personal use talc
16 products, I reviewed the literature on the
17 epidemiology of asbestos and risk of ovarian cancers.

18 And then I informed them that in 2012, the
19 International Agency for Research on Cancer stated
20 that a causal association between exposure to asbestos
21 and cancer of the ovary was clearly established, and
22 that that agency had classified fibrous talc, a
23 component of talcum powder products, as a Class 1
24 carcinogen, the most dangerous level of carcinogen.

25 Q. Dr. McTiernan, so within this last year, you

1 have shared your published opinion on two occasions:
2 Health Canada and Congress. Is that correct?

3 A. Correct.

4 Q. What I would like to do now, Dr. McTiernan, is
5 to move on to the methodology.

6 Her Honor is interested in hearing what the
7 methodology was and is that you employed in order to
8 arrive at your opinions that talcum powder products
9 can cause ovarian cancer.

10 Why don't we pull up the next slide.

11 What I'll ask you to do is walk the Court
12 through your methodology in a systematic way using the
13 chart, if that is helpful.

14 A. Okay.

15 As I would do for any scientific research of
16 this type, what I am trying to look at, an overview
17 and do causal assessments, I would first formulate a
18 question. So I did that.

19 The question in this case is: What is the
20 association between talcum powder products and ovarian
21 cancer?

22 The second question was: Can the use of
23 talcum powder products cause ovarian cancer?

24 I've conducted a systematic review --

25 Q. When you say "systematic review," we heard about

1 systematic reviews. What is it?

2 A. It means you make the effort to look at all
3 available evidence -- in this case, epidemiologic
4 evidence, and that you do a careful searching through
5 a database and through relevant journal articles to
6 make sure you have the totality.

7 To do that, I defined search terms for the
8 database. I conducted a PubMed search. I provided
9 inclusion and exclusion criteria. From all of that,
10 after reviewing all that, I found -- I identified 38
11 relevant original and peer-reviewed epidemiologic
12 publications.

13 As I continued my work on the report, I
14 updated the search and I continued to do that.

15 Q. What is the next step?

16 A. The next step is reviewing the data. So I
17 reviewed relevant epidemiologic studies. In those
18 studies I considered the statistical data, the
19 strength and weaknesses of study type, the effect of
20 possible bias, chance, confounding and differences in
21 exposure measures. I considered dose-response, what
22 we talked about before. I also considered data from
23 non-epidemiologic lines of evidence, such as animal,
24 cell, clinical and pathological studies. I considered
25 non-talc components of talcum powder products and

1 impact on carcinogenicity such as asbestos, fibrous
2 talc, heavy metals, and fragrances.

3 Q. After you had gathered this body of evidence, it
4 included not only epidemiologic evidence but also
5 other sciences that speak to the biological
6 plausibility that speak to cellular studies, animal
7 studies, pathological studies, you moved on to try to
8 aggregate it. Is that correct?

9 A. Yes.

10 Q. Please.

11 A. I extracted data into four tables. We provided
12 those. In my report there is Table H for
13 case-control, cohort, meta-analyses and pooled
14 studies.

15 Q. Putting those tables together that are at the
16 end of your expert report, how did you go about
17 extracting certain study characteristics and why did
18 you do that?

19 A. I chose the study characteristics that would be
20 most important to know about the breadth and depth of
21 individual studies, particularly to be able to know
22 how large the study was, where it was conducted, when
23 it was conducted, how many cases were included, how
24 many people without cancer were included, if it was a
25 cohort, how long it had been followed. I looked at

1 dose-response. The key metric is relative risk.

2 Relative risk is clearly the important element. And I
3 also looked at the statistical testing on cancer
4 subtype.

5 Q. One follow-up. Why was it important, relevant
6 to the study of science that you extract this kind of
7 information from the studies?

8 A. It is relevant in interpreting their final
9 results because these elements influence the results
10 they get and what they might mean.

11 Q. Thank you.

12 Then what did you do?

13 A. Then I conducted what we call a Bradford Hill
14 analysis; and using this analysis, which is a way to
15 assess for causality, I used independent judgment, I
16 weighed relevant evidence, and reached a conclusion.

17 Q. Thank you, Dr. McTiernan.

18 Dr. McTiernan, is the epidemiology you have
19 employed in this case for purposes of developing your
20 opinions recognized and generally accepted by those
21 scientists in your field of expertise?

22 A. It is, yes.

23 Q. Do you in your own research and academic work
24 employ these same types of scientific reasoning and
25 epidemiology that you have used for purposes of

1 developing your opinions in this case?

2 A. I do. Most recently and notably the U.S.
3 Government work I have done for the physical activity
4 guidelines we used a similar process to evaluate
5 literature and do causal analysis and determine what
6 we believe the literature is stating.

7 Q. In the course of talking about the methodology
8 that you employed in order to arrive at the opinions
9 that you have shared and will continue to share with
10 us today and have publicly, you talked about certain
11 epidemiological designs. We're going to have a little
12 teaching session, if you will.

13 To the extent you can tie in any of your
14 thoughts your opinions with regard to talcum powder,
15 you can use those as examples. What I would like to
16 do is take the next probably five, ten minutes just to
17 get a basic understanding of how you are going to be
18 approaching the studies for the Court and explaining
19 what they actually mean. All right?

20 A. Okay.

21 Q. Let's step back and talk about the four
22 different types of study designs.

23 A. The four types of data that are available for
24 this issue -- ovarian cancer and talcum powder product
25 use.

1 The first is case-control studies. This is
2 where investigators would identify individuals with
3 ovarian cancer and then would identify people without
4 cancer, interview both about their use of products and
5 other variables to help with the interpretation, and
6 then they compare what exposure did the cases have and
7 what exposure did the controls have.

8 Q. In this case, exposure to talcum powder
9 products?

10 A. Yes.

11 Q. In this case, what disease?

12 A. Ovarian cancer.

13 Q. Go ahead.

14 A. Modern case-control studies tend to be
15 population-based. The reason for that is to be
16 generalizability. So if you have results from a
17 case-control study, can that refer to what the most
18 likely universe of results would be?

19 Q. Let's step back a little bit.

20 There are two different types of case-control
21 studies.

22 A. Yes, the first is population based.

23 Q. What does that mean?

24 A. It means the cases and controls come from the
25 population. The cases often are identified through a

1 registry, and the controls will be from some
2 population group.

3 A second type of case-control studies is
4 hospital-based, and that's where investigators in one
5 hospital identify all the cases of ovarian cancer that
6 have happened in some period of time.

7 The controls they would select from other
8 hospitalized patients that don't have ovarian cancer.
9 This type of case-control study is less likely to be
10 done.

11 Q. Which one?

12 A. Hospital-based, because you can't generalize it
13 to the general population. And because the controls
14 who are sick and in the hospital may be sick for
15 different reasons than the cases.

16 So, ideally, in a case-control study, the
17 cases and controls would be very similar except for
18 the one exposure you want to look at in this case,
19 talcum powder products. We want to get rid of all of
20 the other kind of noise you could have when you are
21 looking at real people.

22 The second kind of study is a cohort study.
23 This is a study where women are identified at one
24 point, invited into a long-term prospective study.
25 They complete forms when they enter the study,

1 questionnaires; and, in this case, all of those
2 studies were self-administered questionnaires.

3 Q. What is a "self-administered questionnaire"?

4 A. As it sounds, the person completes the form
5 themselves. Case-control studies, usually the data
6 are collected through an interviewer, a trained
7 interviewer. So in the cohort studies, the women
8 enter -- the cohort, they complete the forms, data
9 are collected and they are followed up over time until
10 cancers occur -- in this case, ovarian cancer, because
11 ovarian cancer is rare, you need a couple of hundred
12 thousand women followed for 20 years to find a large
13 number of cancer cases.

14 Q. When you say "cases," there is a difference
15 between the total population that enters the study and
16 those actual cases of cancer?

17 A. Yes. The critical number is the number of
18 cases. I have been involved with the design of
19 several cohorts and you design your cohort to be a
20 certain size in order to have the right number of
21 cases developing. It is the number of cases of
22 ovarian cancer that occur. That's the key variable.

23 Q. Is there also another type of study where we
24 aggregate information?

25 A. Yes. There are two, and one is called

1 meta-analysis. This is where an investigator collects
2 data from published studies. So they get the specific
3 statistics from a published study and then analyzes
4 them and combines them into one summary statistic.
5 They collect this number called relative risk from
6 different studies and they combine those relative
7 risks so they could have one relative risk. It gives
8 you a very big summary of what the literature looks
9 like overall.

10 Q. We'll be talking about those a bit later.

11 What is the next study?

12 A. The next study is a pooled analysis. This is
13 where individual level data are obtained from the
14 individuals in the study, in this case, women. So
15 women with ovarian cancer, women without ovarian
16 cancer. Their data then are analyzed as if it is one
17 large study, and we have then also summary statistics
18 that are developed. It is a very excellent way of
19 looking at data overall.

20 Q. The value of doing an aggregate type of combined
21 study like meta-analyses and pooled would be what?

22 A. You really can see what the picture is overall.
23 You can have much larger numbers. The pooled example,
24 the pooled study we'll talk about has 14,000 cases in
25 it. So you really have enough numbers to see what's

1 going on. You could look at subgroup analyses. You
2 could look at dose-response. There is a lot of
3 advantages to looking at pooled analyses.

4 Q. We'll talk about that a little bit later.

5 Dr. McTiernan, we talked about these
6 observational types of studies. Correct?

7 A. Yes.

8 Q. Is there any type of study you do use in your
9 academic and professional research world and
10 considered but did not utilize in this case?

11 A. Yes. I conduct randomized clinical trials for
12 many different purposes. The Women's Health
13 Initiative had three randomized trials in it. In this
14 case, first, if you did a randomized clinical trial to
15 test where the talcum powder products cause ovarian
16 cancer, first of all, you would need hundreds of
17 thousands of women followed for decades before you
18 would have enough ovarian cancer cases developing.
19 Much more importantly, it would be the ethics, it
20 would not be ethical to test in a randomized trial
21 something you think could be harmful in order to see
22 if it does cause harm. So randomized trials always
23 have to have the goal of can something have a benefit.
24 Q. Thank you. Dr. McTiernan, in your professional
25 research and academic work, do you design and publish

1 all core types of those studies, including randomized
2 control trials?

3 A. I do, yes.

4 Q. In evaluating the totality of the
5 epidemiological data on talcum powder products and
6 ovarian cancer, did you invoke a hierarchy of evidence
7 in order to better examine the association, the
8 relationship between talcum powder and ovarian cancer?

9 A. No, I did not. I looked at the totality. I
10 looked at all of the studies, and I looked at the
11 studies that combined information. I looked at
12 everything.

13 Q. I guess, my question is you have this choice of
14 five studies. You talked about why you didn't look at
15 any randomized control trials. But with regard to the
16 case-control, the cohort, the meta-analyses, and the
17 pooled study, are there reasons that one type of study
18 might be more reliable, specifically when you are
19 looking at the issues you were asked to look at here?

20 A. All of those studies provide useful information.
21 So I considered all of them. I did not place any
22 hierarchy on them. They all give useful information.

23 Epidemiology studies all can have benefits,
24 strengths, and they can all have weaknesses. I
25 considered all of that when I reviewed the data.

1 Q. The defendants here, you read their briefing and
2 suggested you should have made your focus more on the
3 cohort studies rather than you case-control studies.
4 Do you recall reading that?

5 A. I do.

6 Q. Why don't you agree with that?

7 A. There are benefits and drawbacks to all these
8 types of studies. I do not believe for this
9 particular question when you are looking at what a
10 woman has used, and you want to know her lifetime
11 exposure, and you want details, you are going to see
12 that best described in a case-control study that can
13 be focused. The cohort studies have their strengths,
14 and we'll go over those in a bit also. I found both
15 types of studies provided useful information, and I
16 summarized that in my deliberations.

17 Q. In your work as a professional and researcher,
18 is there an example wherein a particular study type
19 was more suited for a particular scientific question?

20 A. There are some instances, and I can give one
21 example. With the World Cancer Research Fund, I sit
22 on a panel that advises them on interpretation of
23 dietary data. Their mission is to focus on diet, and
24 diet is a very interesting thing to try to collect,
25 because if you ask people about their diet and they

1 have already developed cancer -- so in a case-control
2 study you will be asking people with cancer about
3 their diet, and comparing them to controls without the
4 diet. Once somebody develops cancer, their diet
5 changes dramatically. If you want to know what
6 somebody's previous diet effect on cancer risk is, it
7 is very difficult to do that in a case-control study.
8 The person has already changed. Diet, you can't ask
9 somebody what they have eaten in the past. We've
10 tried but researchers found that diet, if you ask
11 somebody at one point what the diet was a year ago,
12 they will tell you what they are currently eating,
13 even though they think it is a year ago, and this has
14 been tested. Diet is one very particular study, a
15 variable. It is complicated. It is not like you are
16 asking somebody how many eggs you ate. The dietary
17 forms in the Women's Health Initiative had 150 items,
18 and for each item you are asking people how often they
19 eat it and how large a serving is. You can imagine
20 how complicated that is, and then if you ask somebody
21 to recall that.

22 So for diet studies, it is really an example
23 of somewhere where a cohort study may be more helpful;
24 ask somebody when they enter the cohort study what
25 their complicated dietary pattern was, and then follow

1 them forward over time. You still have the issue
2 where you need to have a huge study to follow and
3 follow them long enough until ovarian cancer develops.

4 Q. Johnson & Johnson claims your reliance on study
5 science in the case of talcum powder products and
6 ovarian cancer is inconsistent with the work you did
7 with the World Cancer Research Fund, which was
8 involving dietary habits and the need to do at that
9 time a cohort study. Is the work you have done in
10 this case inconsistent with your prior research in
11 epidemiology?

12 A. It is not inconsistent with my overall research
13 of published 17-case-control studies. I have been
14 principal investigator of a case-control study. I
15 participated in a pooled analysis involving my data
16 from case-control studies. I participated in even
17 more cohort studies. Hundreds of publications have
18 come out from the cohort studies that I worked with.
19 So I've looked at studies -- I've used studies across
20 the board in epidemiology because sometimes one study
21 works better than another. Sometimes you do both.

22 Q. And it depends on the study question. Is that
23 correct, Dr. McTiernan?

24 A. Absolutely, yes.

25 Q. I'm going to shift gears a little bit now and

1 talk a little bit now, if you will, ask you to talk
2 about the first group of studies, and that would be
3 -- you talked about some tables you put together. Is
4 that right?

5 A. Yes, for the expert report.

6 THE COURT: Those tables did not come out on
7 my copy.

8 MS. PARFITT: We're not going to be using
9 those at all. It is a question.

10 Q. The reason for that demonstrative, Dr.
11 McTiernan, is just so you could identify for the Court
12 that there were four tables that you put together?

13 A. Yes, they are.

14 Q. And they dealt with data you selected from the
15 four different study types we just talked about.
16 Correct?

17 A. Yes.

18 Q. Did you assist me in taking that data and
19 putting that data together in four plots for the
20 individual studies?

21 A. Yes. You assisted me. I told you what I needed
22 and then you kindly did the forest plot part for me,
23 yes.

24 Q. We're going to get to those in just a moment.

25 Why did you want a forest plot. What was the

1 purpose of plotting it along a forest plot?

2 A. A forest plot is a way to visualize what's
3 happening across studies. It is a commonly used
4 method. If you look at the meta-analysis, trying to
5 see what did the data look like across studies, they
6 will do this, forest plot.

7 Q. Directing your attention to this next exhibit,
8 it is a case-control and cohort study, all ovarian,
9 1982 to 2016. Would you share with us the information
10 that's contained, perhaps giving us, first, a
11 description of the types of information and, then,
12 we're going to talk about how you interpreted that.
13 Fair?

14 A. Okay. I'm going to mark on the PowerPoint what
15 I'm pointing at.

16 This table on this side has the data that I
17 put into my expert report and we put into this slide.

18 The first column is just the Case-Control
19 Study. That's the name of the study and the year it
20 was published.

21 Q. How many of those did you review?

22 A. 28 case control studies. And then the
23 nationality where it was conducted, the numbers of
24 cases. It is a key number to help us interpret these
25 results, how many cases there were.

1 Q. Does that represent cases of ovarian cancer?

2 A. Cases of ovarian cancer, yes.

3 The number of controls, individuals without
4 cancer, whether the study was population-based or
5 hospital-based.

6 The next column says "DR" and that stands for
7 dose-response. The question was, Did that study
8 address dose-responses? Did the risk increase with
9 increasing doses? If they did address it, that would
10 be "yes"; if they addressed it and found a positive
11 response. If they addressed it and found no
12 dose-response, I would put the word "no" in there. If
13 they did not even attempt it we put N/A. And
14 "incomplete" if they attempted it but they had
15 incomplete data -- we'll talk more about dose-response
16 later.

17 The next column is "relative risk." Relative
18 risk is the most important statistic in all of these
19 studies. It refers to what is the risk in exposed
20 individuals compared to somebody who is not exposed.
21 What is the risk in somebody who used talcum powder
22 products compared to somebody who did not. So the
23 relative risk tells us the strength, how large was the
24 association. It tells us consistency when we look
25 across different studies. It's the effect size. It

1 is also called the "point estimate." In some studies
2 you could see the words "odds ratio" or "O.R.". It is
3 the same thing estimating "relative risk."

4 "HR" stands for "hazard ratio." That means
5 the same thing. So I'm always going to say relative
6 risk here for simplicity.

7 The next column and the one following it
8 referred to the confidence intervals, the lower limit
9 and upper limit of confidence interval.

10 Q. Share with us what that means and how it is
11 interpreted.

12 A. The confidence interval in epidemiologic studies
13 is a statistical tool to see how likely the universe
14 of results would fall within a particular interval.
15 If we knew the universe of results. We don't. So we
16 are always estimating. The confidence interval does
17 not affect what the actual relative risk is for that
18 study. It is just an estimate how the truth might lie
19 if we knew everything.

20 Q. You said the confidence interval does not affect
21 at the relative risk. Explain that?

22 A. If you have a small narrow confidence interval,
23 if you have a wide one, if it crosses one, none of
24 that is going to affect what the actual relative risk
25 says. The relative risk always says risk in talcum

1 powder use versus risk without. That's a key
2 comparison. The confidence interval is a statistical
3 tool that helps us interpret. Confidence intervals
4 can range widely. They will always be around the
5 relative risk.

6 Q. Can you give us an example.

7 A. Look at the top one. That studies relative
8 risk. It was approximately 1.4. I should explain.
9 Along the very bottom here we have numbers that refer
10 to a number, that's a relative risk. A risk of one is
11 no effect, no association. If it is a relative risk
12 of 1.2, that would be a 20 percent increased risk for
13 users versus nonusers. If it is to the left of the
14 line, it would be a lower risk in users versus
15 nonusers. If the confidence interval crosses 1, so if
16 it includes one --

17 Q. Take an example where it crosses 1.

18 A. You can see right here it's called Moorman.
19 That study's relative risk was to the right of the
20 line. It was a positive relative risk. But the
21 confidence interval crossed the line, so it suggests
22 in the universe the relative risk can fall below 1.
23 It could be a negative risk or it could increase risk
24 because the line also goes to the right.

25 Q. A situation or study like that where the

1 confidence interval, the lower bound is below 1, the
2 upper bound is above 1, you now said crossed 1. Is
3 that correct?

4 A. Yes.

5 Q. What does that do to the significance of the
6 relative risk, the relative risk is above 1?

7 A. It doesn't change the relative risk at all. It
8 tells you in the universe, if you knew every person
9 who had ovarian cancer or not, you would have a
10 95 percent chance of it falling somewhere in that line
11 in that confidence area. It is an estimate where a
12 relative risk might lie.

13 Q. Is that reliable information, information that
14 scientists should recognize and consider in their
15 evaluation of studies?

16 A. It is useful, yes. The statisticians tell us
17 not to use it to determine if there is an effect or
18 not or what the effect size is. They tell us it is
19 always the relative risk, and that's how I have
20 interpreted it.

21 People use this -- many scientists use this
22 term "statistical significance." Statistical
23 significance wasn't invented by statisticians who
24 invented the tools. It was more people that apply it,
25 and some people will say that a study is not

1 statistically significant if the confidence interval
2 includes one if it extends across that line.

3 Q. Dr. McTiernan, does a nonsignificant relative
4 risk, meaning that the confidence interval is less
5 than 1, mean that there is no association between the
6 exposure, in this case talcum powder products, and the
7 outcome ovarian cancer?

8 A. It does not. The association is driven by the
9 relative risk. The confidence interval tells you how
10 likely, if you did know everything, that the relative
11 risk would fall within that confidence interval.
12 That's why it is called confidence interval -- how
13 confident you could be that's where it would fall if
14 you knew the totality of evidence.

15 The one thing -- there are two things that
16 determine what the confidence interval is. One is how
17 large the sample size is. Large sample size is always
18 better because it gives you more precision. You are
19 more confident your relative risk falls within the
20 confidence interval. Confidence intervals tend to be
21 smaller in the very larger studies.

22 The other thing that drives it is variability
23 around the average measure.

24 Q. What do you mean by that?

25 A. How variable were the numbers; was there a lot

1 of noise in the data. And so much of that is driven
2 by sample size again, and some of it is driven just by
3 the nature of the data.

4 I've looked at thousands of forest plots in my
5 daily work. I look at them all the time. It is
6 unusual for a forest plot to show this distribution
7 when most things are to the right of the line --

8 Q. Can you show us again?

9 A. -- to the right of 1.0. This tells us we have
10 quite a bit of consistency across the studies.

11 Q. Is that to the right of the line?

12 A. To the right of the line.

13 Most of the studies, almost all, except for
14 two studies, each of those dots refer to a study with
15 a couple of exceptions, almost all those dots, each
16 dot refers to the relative risk, and almost all of
17 them and to the right of the line with two studies
18 exception, one case-control study and one cohort
19 study. There are a couple of studies that are
20 referred to twice here because they provided their
21 data separately for subgroups.

22 For example, Moorman was a study in white
23 women and black women and that presented the data
24 separately. We couldn't combine it. Booth presented
25 data separately for daily and weekly use, and there

1 wasn't a way to combine them.

2 Q. Dr. McTiernan, you were talking about the
3 case-control. Below that dark black line we have some
4 other studies.

5 A. I was just about to get to that. The cohort
6 studies we put separately because some of the data is
7 a little bit different. In the cohort study, we put
8 the name, the nationality, the number of the cases --
9 again, a key variable. And the next column says
10 "noncases." These were women in the cohort who did
11 not develop ovarian cancer.

12 The following column is the follow-up years.

13 The next column -- the next few columns are
14 the same as above. Dose-response is addressed or not,
15 relative risk, and the confidence interval.

16 Q. How many cohort studies did you evaluate?

17 A. This represents three cohort studies, even
18 though there are five lines there. Gonzalez was from
19 the Sister Study, Houghton was the Women's Health
20 Initiative study I'm very familiar with, and the
21 following three -- Gertig, Gates, 2008, 2010 -- all
22 come from the Nurses' Health Study. Three
23 publications from one study.

24 Q. I think you mentioned the cases would be the
25 number of ovarian cancer cases regardless of the

1 number of women that were enrolled?

2 A. That's right. Again, it is the key variable for
3 knowing how to interpret these studies. Gertig 2000
4 when that study was published, there were 307 cases.
5 The next study, Gates 2008, they chose 210 of those
6 cases to put in another study. It is not really an
7 update. Gates 2010 had followed the women longer, and
8 by that time there were 797 cases.

9 Q. We'll discuss those a little bit more in a
10 little bit.

11 While you were discussing the tables and the
12 relevant parts of that table, there is something
13 called the p-Value. What is the p-Value?

14 A. The p-Value is not presented here but some
15 studies did show them in the data. P-Value is another
16 statistical tool that gives us an idea of how to
17 interpret data. So a p-Value refers to the likelihood
18 of rejecting hypothesis that there is no association.
19 We call that the null effect. That's exactly what the
20 p-Value is. So the p-Value ranges between zero and 1.
21 If a p-Value is, for example .05, that tells us that
22 on an estimated five times out of 100, we would make a
23 mistake by saying there is an effect when there really
24 was no effect. That's a small amount. If a p-Value
25 was .5, that tells us half the time we would make a

1 mistake by rejecting this, what we call null
2 hypothesis.

3 The statisticians that developed the tool
4 advised that people present what the p-Value is rather
5 than using any particular cut point.

6 Q. "Cut point"?

7 A. Yes.

8 Q. What does that mean?

9 A. Some scientists over time have developed -- I'm
10 trying to think of the word.

11 Q. Convention?

12 A. (Continuing) -- convention. Thank you. Have
13 commonly used a p-Value at certain levels and said
14 above that level is not statistically significant.
15 Below that level is statistically significant.

16 Q. And what's that number, what's that convention?

17 A. There are several conventions, but one that is
18 commonly used is P equals .05. If it's that or less
19 some people would say that's a statistically
20 significant result. If it is above that, they will
21 say that is not statistically significant.

22 Q. What is the difference between a p-Value that is
23 less than .06 versus a p-Value that is less than .05?

24 A. Virtually nothing. It just means six times out
25 of 100 you would make a mistake by rejecting the

1 hypothesis that there is no effect versus five times
2 out of 100. So, in reality, the statisticians tell us
3 and the American Statistical Association came out
4 clearly saying this is what you should do is say what
5 the p-Value is and not use a line in the sand to say
6 one is a valid result and one is not a valid result;
7 one is reliable and one is not reliable. We don't
8 talk about p-Values here in the relative risk for
9 individual study. But later on, when we talk about
10 dose-response, we will be presenting some p-Values.

11 Q. Would it be appropriate as a scientist to
12 dismiss studies due to their p-Value?

13 A. I believe it would be especially when you are
14 looking in the totality of evidence than to say one
15 study is statistically significant and one is not,
16 and, therefore, to dismiss the one where the p-Value
17 is greater than something doesn't give you the full
18 picture. You really need the full picture.

19 Q. Would it be inappropriate methodology to dismiss
20 as a finding a result that is not statistically
21 significant?

22 A. To dismiss a study that is not significant, not
23 statistically significant? It would be inappropriate
24 to dismiss that, yes.

25 Q. It would be inappropriate?

1 A. Inappropriate.

2 Q. Dr. McTiernan, looking at this forest plot of
3 both case-control and cohort studies, what does the
4 data from this forest plot of the epidemiological
5 studies that you reviewed both case-control and cohort
6 tell us about the consistency of the data from your
7 review?

8 A. It tells me it is remarkably consistent because
9 you could see that almost all of those relative risk
10 data points are to the right of the line. They are
11 all indicating increased risk in ovarian cancer in
12 women who used talcum powder products compared to
13 women who do not use them.

14 Q. That's regardless of study design. Is that
15 correct?

16 A. Yes.

17 Q. Did you evaluate the role of chance as a
18 possible explanation for these study results, and if
19 you would tell us what does chance mean?

20 A. You evaluate chance by looking at totality of
21 evidence. You can't really tell chance by any of
22 these individual statistics. It is not the correct
23 way to evaluate a statistic to say it only tells you
24 about chance. The p-value is really just how
25 incorrect would you be to reject a null hypothesis.

1 Q. Now, in addition to the cases of all ovarian,
2 did you look at any subtypes of ovarian cancer?

3 A. We did. There are different types of ovarian
4 cancer. 90 percent of ovarian cancers are epithelial.
5 That's the surrounding area, the outside area of the
6 ovary. Of those 70 are what we call serous, and there
7 are smaller percentages of other types of cancer.
8 There is enough data in several studies to look
9 separately at those women who develop serous ovarian
10 cancer compared to those -- in this case compared to
11 controls.

12 Q. From your review of the case-control and cohort
13 study, looking at serous ovarian cancer, were you able
14 to render an opinion regarding the consistency of
15 those study results?

16 A. Yes. This slide has both the overall on top but
17 then the serous cancers on the bottom. You really can
18 see again remarkable consistency. The relative risks
19 are all to the right of the line under serous. You
20 really see it is a consistent finding.

21 Again, on this slide we also just indicated
22 the relative risk and the confidence intervals. You
23 see this across the study types. You do see wide
24 confidence intervals for the serous, and that is
25 because these sample sizes are much smaller than for

1 the overall cancers. You can see this in this
2 graphic. If you compare the top, they tend to have
3 more narrow confidence intervals, more precise. It is
4 wider in the bottom because they are smaller studies.
5 Sample size really matters. The reason why they are
6 smaller, only about half the women in the studies that
7 can look at this were serous.

8 Q. Again, to be clear, for instance, at the top
9 when you have that tight line, is that more precision
10 or less precision?

11 A. More precision.

12 Q. Of the smaller line?

13 A. Yes.

14 Q. Give us an example. And a broad line would
15 suggest what?

16 A. A broad line tells me it is a smaller sample
17 size and that there is less precision in that
18 estimate. But, again, it doesn't affect the relative
19 risk. It just affects what might happen in the
20 totality of what the real result might be if you had
21 the universe.

22 Q. Dr. McTiernan, now that we have looked at the
23 data from the case-control and the cohort studies --
24 and would you call that source data?

25 A. Source studies.

1 Q. -- is there a standardized way to look at the
2 source studies overall or in the aggregate?

3 A. Yes. Meta-analyses are very useful, and in this
4 case we have seven meta-analysis that had been
5 published by the time I prepared my expert report, and
6 an additional study was made public after my report
7 was published. That's the one at the top called
8 Taher.

9 Q. You published meta-analysis and pooled analysis?

10 A. I have, yes.

11 Q. Tell us the importance or not of the information
12 that you gleaned from the meta-analysis and the pooled
13 studies, its advantages and disadvantages.

14 A. So we presented much of the same data on this
15 slide for the individual studies with some
16 differences. So, again, the study name and year is
17 presented. We also wrote the number of studies
18 available in the next column. This study, if you look
19 at the first meta-analysis that was published in 1992,
20 there were only six studies available at that time.
21 As we go up by year, you see more studies available.
22 By the time we get to the most recent meta-analyses,
23 they have the largest number of studies. 27 studies
24 in each one.

25 Q. As you move up from Harlow in 1992, are you

1 looking at the same study, the studies that were
2 included in Harlow and some additional studies?

3 A. Yes. Each newer meta-analysis would subsume the
4 other studies below. So we look at all of the
5 studies. It is important to look at them and see what
6 was the knowledge at the time it was published. But
7 the most valid, in my opinion, studies to look at are
8 going to be the three most recent. They all have 27
9 studies in them. They are very comprehensive.

10 We also included the number of cases in the
11 next line where they were available. You can see from
12 the top two studies we have many more cases available
13 than were available for the individual source studies,
14 17,000 and 14,000 respectively.

15 Q. Those are actual cases of ovarian cancer?

16 A. Cases of ovarian cancer, yes.

17 Then we looked at whether they evaluated for
18 dose-response and then what the summary relative risk.
19 This is a relative risk calculated from the individual
20 studies data and their confidence intervals.

21 Q. What does this information with regard to the
22 relative risk of the studies -- how does this inform
23 your opinion with regard to the totality of those
24 meta-analysis and pooled studies?

25 A. This really helped form my opinion because I was

1 able to see what the data looked like overall, what's
2 the overall summary of what is happening in terms of
3 risk of ovarian cancer in talcum powder product users
4 compared to non-users.

5 Q. What information does it provide you with regard
6 to the strength of the studies?

7 A. It tells me the strength because of the
8 consistency across those studies and it tells me a
9 precise number. I like to think, What is the relative
10 risk? In this case it ranges between, for the most
11 comprehensive studies, this ranges between 1.22 to
12 1.31. That's between a 22 to a 31 percent increased
13 risk of ovarian cancer in product users versus
14 non-users.

15 Q. You got Langseth there that says 1.35?

16 A. Langseth was older and there are 20 studies
17 there. So it's not the most comprehensive.

18 Q. You have Terry below there under pooled. Did
19 you consider the totality of the meta-analysis and the
20 pooled analysis?

21 A. I looked at both. Terry is different. We have
22 it separate because it is a different type of study.

23 The pooled analysis, again, is when
24 investigators share the actual data with the
25 coordinating center. They have the opportunity of

1 having all the data on talcum powder products and on
2 ovarian cancer, but they also have information about
3 other variables to adjust their study for different
4 variables in case that could affect the result.

5 Q. When you adjust their study for different
6 variables what are you speaking of?

7 A. Sometimes in studies with humans when you are
8 trying to determine what effect some variable might
9 have on disease, there could be intervening variables.
10 We call them potential confounding variables. That's
11 the type of variable if it is associated both with the
12 disease and with the exposure it could be influencing
13 results.

14 Q. Give an example.

15 A. An example might be, a commonly used example is
16 cigarette smokers and lung cancer. If you did a study
17 and you determined that individuals who carry matches
18 have increased risk of lung cancer, you may be
19 misinterpreting the data. And it is really about
20 smokers who carry matches, and it is the smoking that
21 causes lung cancer.

22 That is just one example. In that case, you
23 might want to adjust for those variables, and you find
24 out matches don't cause lung cancer.

25 Q. As you reviewed the various studies, did your

1 part of your systematic analysis include ruling out --
2 rather, examining the studies to see whether or not
3 confounding was addressed and whether it was adjusted
4 for confounding?

5 A. I looked at that. In all but one of the
6 case-control studies presented the information on
7 confounders. The problem with confounding, you can't
8 assume from reading the paper that these are all the
9 potential confounding variables because the studies
10 will present the confounding variables and they will
11 present them for their data for their own study; and
12 you can't assume something should be a confounder, if
13 it wasn't in that study. It's always study specific,
14 the confounding.

15 I did go through the exercise of looking at
16 those individual studies that had reported on when
17 they took the confounders into account and when they
18 didn't, when they had a relative risk that was just a
19 plain old relative risk and then had one that was
20 adjusted for these confounders and ten presented both
21 of those types of data, and the relative risks were
22 almost identical in all but one, and that one only
23 changed, that relative risk changed a small amount.
24 That tells me if the relative risks don't change with
25 adjusting for confounding, then it really wasn't a

1 problem in their study. If the relative risk looks
2 the same after adjustment, then it didn't affect the
3 relative risk.

4 Q. Thank you.

5 A. That was one of the benefits of a pooled
6 analysis. You can check all that information and you
7 can adjust fully for all of the potential confounders
8 you know about.

9 The Terry study, it's a pooled analysis, and
10 it tells us they had 8,525 cases, a large number, and
11 it tells us they found a 24 percent increased risk of
12 ovarian cancer in using the statistical term, it was
13 statistically significant because the confidence
14 interval does not include one.

15 Q. Dr. McTiernan, one last question, and we will
16 keep moving in the interest of time.

17 Looking at the relative risk for all the
18 meta-analysis and the pooled analysis, did any of the
19 lower bound confidence intervals, were any below 1?

20 A. No.

21 Q. What if any information did that provide?

22 A. If you use the common terms, it would be the
23 always statistically significant. The ones at the top
24 have -- are much more narrow and that tells me sample
25 size is bigger. There is more precision to those

1 estimates in the most recent ones. So I relied more
2 heavily on those more recent meta-analyses and the
3 pooled analysis.

4 Q. Before we go on and touch on the various
5 studies, I believe you -- did you do a forest plot for
6 the serous group?

7 A. Yes.

8 Q. Again, why did you select serous versus some
9 other type of epithelial ovarian cancer?

10 A. It was the most common subtype available in
11 these various studies, the most common data and most
12 common presented in these studies. It accounts for
13 about half of all ovarian cancers. It is a very
14 relevant one to present.

15 Q. If you can sum up what this information tells us
16 with regard to the study findings.

17 A. It suggests the relative risk of serous ranges
18 between 1.24 -- I'm going to say 32 because while
19 Taher influences me, it is not yet published, but it
20 is very interesting it is also in the same range. So
21 increased relative risk of serous cancer with talcum
22 powder product use. The confidence intervals are
23 narrow. It tells me it is a precise estimate.

24 Q. What does that information tell you about the
25 strength of the evidence?

1 A. It tells me exact numbers. I like to use that
2 to know what the exact level of increased risk is,
3 1.22 to 4-to-1.32.

4 Q. You look at the number?

5 A. I look at what the relative risk is telling us
6 what the data is showing.

7 Q. So strength, in your opinion, is equated with
8 the relative risk number. Is that correct?

9 A. Yes.

10 Q. You've talked about the various case-control,
11 cohorts, meta-analysis, pooled analysis. What is
12 replication?

13 A. Replication would be different, in different
14 types of research. But in epidemiology we don't just
15 replicate results. We look at totality of evidence.
16 So somebody might publish a study. We wouldn't
17 necessarily design and produce an exact replica of
18 that. What we do is determine a question, design a
19 study, look at important variables, and then look at
20 results. But when you see similar findings across
21 different studies, across different areas, that is
22 akin to replication. It tells you that you have
23 reliable findings.

24 Q. Dr. McTiernan, what I want to do now is just
25 move briefly into a few of the studies, if I may.

1 First, is there a perfect study?

2 A. No.

3 Q. How many cohort studies did you say you looked
4 at?

5 A. The three cohort studies.

6 Q. Did you examine for purposes of your opinions
7 not only the three cohort studies, but their strengths
8 and weaknesses?

9 A. I did, yes.

10 Q. Did you do that as well for the case-control
11 studies?

12 A. I did.

13 Q. Briefly walk us through the cohort studies, tell
14 us the basic background, what the strength and
15 weaknesses are. And we're going to do the same
16 generally about the case-control and then move on to
17 Bradford Hill.

18 A. The three cohort studies were conducted in this
19 area. The first was Nurses' Health Study. In their
20 analysis they included 78,000 women. By the time they
21 did their analysis, they had 307 cases of ovarian
22 cancer developed. They collected their information on
23 the talcum powder product use in 1982. They did not
24 update it. Their question was on powders in general.

25 Q. The questionnaire?

1 A. The questionnaire was on powders in general
2 including talc and other powders. It was not updated.
3 They asked about ever use, how often they used it, but
4 they didn't ask for how long they had used it.

5 Overall, for ovarian cancer they found a
6 relative risk of 1.09. They did not see a
7 dose-response.

8 And for serous, they found a relative risk of
9 1.4. So this was comparing users versus non-users.

10 Q. How do you evaluate those numbers? Are those
11 positive numbers? Negative numbers?

12 A. Yes. Both in the positive direction for
13 confidence interval for ovarian cancer including 1;
14 confidence interval for serous did not include 1.

15 Q. So for serous ovarian cancer, if you use the
16 nomenclature "statistically significant," was that
17 study statistically significant?

18 A. Yes.

19 Q. For ovarian cancer, was that a positive or
20 negative finding?

21 A. It was a positive relative risk, but not
22 statistically significant, if you use the criteria of
23 crossing 1.

24 So strengths of cohort study for this specific
25 instance that it limits recall bias. Recall bias is a

1 theoretical problem for case-control studies. If
2 cases remembered use of something of a talcum powder
3 product differently than controls do, a prospective
4 cohort study is unlikely to have recall bias because
5 the women don't have ovarian cancer when they enter a
6 study.

7 There were some weaknesses, and I've listed
8 them here. They were missing quite a bit of data.
9 They didn't ask about duration of use. Their
10 exposures were potentially misclassified because they
11 didn't update. If somebody was classified as a
12 nonuser at study entry and they started using, you
13 wouldn't know that. If they were classified as a user
14 and stopped, you wouldn't know that.

15 Q. What would that do to the relative risk?

16 A. It would attenuate it, lower it. It would make
17 it look like it's closer to 1 than it is in fact.

18 This is an issue for incomplete data for
19 either case-control or cohort studies. In these cases
20 where the cohort studies did not update their data, we
21 call that that they had insufficient exposure level,
22 and it could make the relative risk look lower.

23 Q. The relative risk may look lower than what it
24 actually is?

25 A. Yes. Small sample size gave it insufficient

1 power, and power is a statistical term to describe how
2 you need larger sample sizes to find the relative
3 risk, and it was nurses only.

4 I won't talk about the middle study. It was
5 really just a subset for doing a genetic study.

6 Gates 2010, they followed women until they
7 developed ovarian cancer, by this time 797 women. All
8 of the issues about this study are the same as the
9 first publication with one exception. Under
10 "findings" they chose to use a different way of
11 classifying the participants. So instead of comparing
12 users to non-users, they added together women who had
13 used a little bit, who had used less than once a week
14 to the non-users.

15 Q. So in Gates 2010, they combined someone who was
16 not a user with someone who might have used the
17 product less than one week?

18 A. Yes.

19 Q. What does that do to the relative risk?

20 A. That would attenuate the relative risk as well.

21 Q. It could drive the risk down?

22 A. Yes.

23 Q. Please.

24 A. So, otherwise, the other issues are the same.

25 They found a relative risk of 1.06 for overall ovarian

1 cancer and for serous ovarian cancer.

2 Q. That relative risk of 1.06, is that a positive
3 relative risk?

4 A. It is in the positive direction confidence
5 intervals include one.

6 Q. The weaknesses that you just discussed with
7 Gertig 2000 would be very similar with Gates 2010. Is
8 that correct?

9 A. Yes.

10 Q. Let's move to the next cohort study that you
11 reviewed.

12 A. This is the Women's Health Initiative, one I
13 know very well because I was the project director and
14 very involved with this study when the questionnaire
15 was developed, and procedures and protocols were
16 developed.

17 Q. How long were you involved in that study?

18 A. 15 years altogether. I was project director for
19 five years; and after that I continued to lead the
20 outcomes evaluation part of the study. So this study
21 had 93,000 women when it began; and by the time the
22 data collection was completed for this particular
23 study, 429 cases of ovarian cancer had occurred. The
24 women completed information on use of powders similar
25 to the Nurses' Health Study by self-administered form

1 and by asking about general question about powders to
2 the private area. The questionnaire asked about
3 duration but not frequency.

4 Q. What's the follow-up to that?

5 A. 12 years. And, again, it was not updated. So
6 if somebody changed their exposure, you wouldn't know
7 it. If they became a user, you wouldn't know it. If
8 they became a nonuser, you wouldn't know it. The
9 impact of that is to lower the relative risk or to
10 move it closer to 1.

11 Q. What were the findings?

12 A. For all ovarian cancer there is a 12 percent
13 increased risk similar to serous cancer, 13 percent
14 increased risk, but the confidence intervals included
15 1, positive relative risk.

16 Q. Weaknesses? Strengths?

17 A. Strength, again, limits recall bias. The
18 weaknesses are very similar to what we see for the
19 Nurses' Health Study. There is a power issue because
20 of the small sample size. Here sample size is key,
21 the number of cases that develop. In a cohort study,
22 the only reason for enrolling so many women in a study
23 is to get enough cases. In this case 429 cases is the
24 important number. It was small compared to what you
25 need.

1 Q. Going through those five weaknesses, missing
2 data, what does that do to the relative risk? Does it
3 drive it higher?

4 A. It would drive it lower, make it weaker, closer
5 to 1.

6 Q. Exposure, not updated. What would that do to
7 the relative risk?

8 A. Same thing. That would be part of incomplete
9 exposure information, it would attenuate it down.

10 Q. Insufficient power number of cases?

11 A. Same thing. Not enough numbers. It is more
12 difficult. If you have a smaller sample size, it is
13 more difficult to find the relative risk in this range
14 that we're looking at. We're looking at relative risk
15 1.2 to 1.4; and to find that in studies, you need a
16 larger sample size.

17 THE COURT: I have a question, Dr. McTiernan,
18 before we go on.

19 For instance, when you indicated incomplete
20 dose-response analysis, you said you were the project
21 director for this. You pointed out these are
22 weaknesses. Why was it constructed in this way?

23 THE WITNESS: Excellent question. The Women's
24 Health Initiative was designed like many cohorts to
25 look at so many different outcomes, heart disease,

1 fractures, breast cancer, colorectal cancer. So we
2 had to look at variables, risk factors for all of
3 those.

4 So in an ideal form questionnaire you would
5 have details on every single variable to a great
6 degree, as much data as you can collect. This was a
7 government contract, and the government limited how
8 many pages we could ask the women to complete. It was
9 a paper issue. And so we really -- the committees
10 that worked on this had to limit the length of the
11 questionnaires, and that meant limiting how much
12 information we could collect on each question.
13 Perineal products use is really only relevant to
14 gynecologic cancers. It wasn't asked for purpose of
15 looking at heart disease or breast cancer.

16 THE COURT: So what you're telling me, this
17 was an initiative that was not specifically directed
18 towards talc and ovarian cancer. There were a lot of
19 other health issues being addressed, a much broader
20 study?

21 THE WITNESS: Yes. You described it much
22 better than I do. Thank you.

23 But the same is true for the Nurses' Health
24 Study and Sister Study. They weren't designed
25 specifically for ovarian cancer. By design,

1 case-control studies are designed for ovarian cancer.
2 That's one of the strengths of a case-control study,
3 strength of a cohort study, is that it is prospective,
4 limits this recall bias issue.

5 THE COURT: For a cohort study, that was only
6 directed to the one issue that would be different?

7 THE WITNESS: If you could do that, yes.
8 There aren't too many, but some of them do.

9 THE COURT: Thank you for clarifying there are
10 other studies broader based as well.

11 BY MS. PARFITT:

12 Q. Let's move on to the last cohort study that you
13 examined.

14 A. Gonzalez was the cohort study called the Sister
15 Study, and to be in the study an individual had to
16 have a sister with breast cancer; and this is a
17 government-run study, and the main goal is to look at
18 risk factors for breast cancer.

19 So the sample size is designed for breast
20 cancer, and many of the questions are designed for
21 breast cancer. They asked women when they entered the
22 study whether use of talc was in the 12 months before
23 enrollment, and they followed the women for just six
24 years before they decided to analyze these data.

25 Q. 12 months before the study, what is the

1 significance of that?

2 A. It is very low exposure data, and the resulting
3 data are consistent with that. Only about 13 percent
4 of women said, Yes, I used talc, because they only
5 asked about 12 months. So if they asked about
6 lifetime or ever, they might have gotten a larger
7 number, but they only found out for 12 months.

8 So by the time they followed these women over
9 six years, they had 154 cases. One thing that's very
10 important about this study is that they didn't confirm
11 many of the cases. They only confirmed about two
12 thirds in fact had ovarian cancer. I didn't mention
13 the other two cohorts were very good and did confirm
14 ovarian cancer. That's really critical to know: Did
15 this person really have ovarian cancer? So the
16 results are no dose-response information in the study.

17 Q. Some people have referred to this as the
18 "douching" study. How did douching weigh into the
19 results of the Sister Study?

20 A. They did find douching did increase risk. It
21 was also douching in the last 12 months. But then
22 they adjusted for that variable and other potential
23 confounders and found it didn't affect the results.
24 With or without adjustment for douching, the relative
25 risk was approximately .7. It was below 1, but it

1 didn't change by adjusting for it or not.

2 Q. So based upon this study, what information does
3 it provide you with regard to studies in general,
4 adjusting or not adjusting for douching, and how that
5 might impact study results?

6 A. It tells us for this study it was not a
7 confounder. It didn't affect, even though it was
8 related to the disease and related to the other
9 exposure, it didn't make any difference to adjust for
10 it.

11 In terms of strength, the same strength as the
12 other cohort studies. One of the main issues in my
13 mind is the very small sample size, 154 cases only,
14 and that there was a poor confirmation of cancer
15 diagnosis.

16 Q. What would those limitations do to the relative
17 risk?

18 A. Again, it would attenuate relative risk.

19 Q. Let's move quickly, if we can, to the
20 case-control studies, and then we'll try to get down
21 the home stretch here.

22 There are some case-control studies we're not
23 going to describe each individual one. Did you take
24 into consideration the limitations and strengths of
25 all of the case-control studies as well?

1 A. Absolutely, and I wrote about each one in my
2 report.

3 Q. In the meta-analyses and the pooled?

4 A. Yes.

5 MS. PARFITT: Your Honor has your report.

6 Q. So if you can briefly discuss what they are and
7 we could move on.

8 A. Strengths of this is the ascertainment of cases
9 was excellent. I should mention the control of the
10 cohort studies, two of them had excellent
11 ascertainment of cases. Most of the case-control
12 studies had detailed lifetime exposure information on
13 talcum powder product use. Many were
14 population-based, and those are generalizable to the
15 population from which they are taken.

16 The larger case-control studies had what we
17 call sufficient power to determine the relative risk
18 that we are looking at, 1.2-to-1.4. The potential
19 limitations, some of them did have insufficient power,
20 some were very small, especially the older studies.

21 As the newer studies came along, they realized
22 they needed to make their studies larger, and there
23 were. There was some potential for exposure
24 misclassification here as well, if the study didn't
25 ask about fully, about lifetime use or if the women

1 didn't recall.

2 Case-control studies always have the potential
3 for recall bias. Some methodologists say that's more
4 of a theoretical reason.

5 Q. What does recall bias mean?

6 A. If the cases remember something more or more
7 easily than do the controls, there could be a bias
8 between their findings, between their results. Again,
9 the methodologists that look at this say it is more
10 theoretical but it is still something to consider.

11 Q. Based upon your review of all of these
12 case-control, cohort studies, the study designs, what
13 is your opinion with regard to whether or not recall
14 bias impacted study findings?

15 A. I think it is less likely because you have such
16 consistency across studies. What is interesting is
17 that within studies, those that we're able to look at
18 type of ovarian cancer, this finding was seen only in
19 epithelial ovarian cancer, not in the other types.
20 There is a small number of cases that were not
21 epithelial. You didn't see that association with
22 talcum powder product use. If a woman with ovarian
23 cancer is more likely to recall use of these products,
24 you would expect to see it across all types of ovarian
25 cancer and you didn't see it in all types.

1 Q. And you didn't see that?

2 A. And you didn't see it in all types. In all
3 epidemiologic studies there is potential for
4 confounding, and that's when an intervening variable
5 is affecting the results. So I considered that in all
6 and looked to see whether they had adjusted for
7 confounding.

8 Q. Dr. McTiernan, in spite of all the limitations
9 and strengths you considered with regard to the
10 epidemiological studies, are you confident in your
11 opinions talcum powder products cause ovarian cancer?

12 A. I am, yes.

13 THE COURT: Let's take our break now.

14 THE DEPUTY CLERK: All rise.

15 (Recess.)
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1 THE DEPUTY CLERK: All rise.

2 THE COURT: Thank you.

3

4

5 **ANNE MC TIERNAN**, resumed.

6

7 DIRECT EXAMINATION (continued)

8 BY MS. PARFITT:

9 Q. Dr. McTiernan, when we took the quick break, we
10 were about to begin a discussion about the methodology
11 you employed for assessing talcum powder products can
12 cause ovarian cancer. What is the methodology you
13 employed in order to make your causality assessment?

14 A. I applied a Bradford Hill causation process
15 which involves investigating several aspects of
16 causation. I looked at strength, temporality,
17 coherency, specificity, dose-response, experiment,
18 consistency, plausibility and analogy. And then I
19 weighed the evidence and made a conclusion.

20 Q. These Bradford Hill guidelines, are these
21 guidelines that are generally-accepted and recognized
22 by scientific bodies, both nationally and
23 internationally?

24 A. Yes.

25 Q. Are they a checklist of items?

1 A. No, they are not.

2 Q. What are they?

3 A. They are aspects to consider. Some may be
4 important for an issue and some may be less important.

5 Q. For purposes of your opinion, did you consider
6 all of the nine factors?

7 A. I did consider them all.

8 Q. I would like to have you walk us through the
9 various aspects that you considered. We already
10 talked and spent some time on the first one, strength.
11 My question to you is, did you, for purposes of your
12 opinion on causality, assess the strength of your
13 association?

14 A. I did.

15 Looking at the data overall, I concluded the
16 risk of ovarian cancer was increased by 22 to
17 31 percent in users of these products compared to
18 non-users.

19 Q. Is there a minimum relative risk?

20 THE COURT: What was the percentage again?

21 THE WITNESS: 22 to 31 percent.

22 THE COURT: Thank you.

23 Q. Is there a minimum relative risk for a
24 determination of causality?

25 A. There is not.

1 Q. Dr. McTiernan, are there other examples of
2 exposure and disease where the associations are
3 similar to the associations you saw with talcum powder
4 products and ovarian cancer, briefly?

5 A. There are several. A couple that are relevant,
6 the Women's Health Initiative Clinical Trial --

7 MR. WILLIAMS: Your Honor, I don't believe
8 this is in the report. We are checking now. I don't
9 believe it is in the report.

10 THE COURT: Ms. Parfitt.

11 MS. PARFITT: The two she picked were in the
12 report. Do you want me to come back to that question?

13 MR. WILLIAMS: That would be great.

14 THE COURT: If there is an objection, you just
15 stop talking until we rule on it.

16 THE WITNESS: Okay.

17 THE COURT: Thank you.

18 Q. You were starting to talk about HRT. Was that
19 in your report?

20 MS. PARFITT: I have it in the report, page 26
21 and 27.

22 MR. WILLIAMS: Thank you, your Honor.

23 THE COURT: SO we're back to the same
24 association question.

25 BY MS. PARFITT:

1 Q. A couple of examples, and the first one you
2 started to speak about was HRT?

3 A. The Women's Health Initiative Clinical Trial
4 found a relative risk of 1.26 in women assigned to a
5 hormone therapy for five years compared to placebo.
6 An observational study found a relative risk of 1.6
7 for HRT use. This is for risk of breast cancer.

8 Q. Any other examples?

9 A. Another example is exposure to secondhand smoke.
10 I also found a relative risk in the similar range.

11 Q. A similar range of the 1.2 to 1.31?

12 A. Yes.

13 Q. Let's move on to the next Bradford Hill aspect.
14 This would be consistency. Again, we talked quite a
15 bit about the consistency earlier on in our
16 discussion. What is your opinion with regard to
17 whether or not the Bradford Hill consideration of
18 consistency was met based upon your evaluation of the
19 literature and study you did?

20 A. Across the studies -- and you could see it
21 visually in the forest plot. There is a consistent
22 increased relative risk across studies for those who
23 were talcum powder users compared to non-users.

24 Q. Over what period of time?

25 A. Over from 1982 through 2016 and the results were

1 consistent across countries and across races and
2 ethnic groups as well as consistent within the studies
3 themselves. You also see the same consistency with
4 serous cancer. What is clear is that the important
5 thing to look at for consistency is the effect size,
6 the relative risk. That determines consistency of
7 results in epidemiologic studies.

8 Q. Let's move to a concept we haven't talked too
9 much about and biological plausibility. Did you
10 consider biological plausibility for purposes of your
11 causation assessment?

12 A. I did.

13 Q. What is biological plausibility?

14 A. Biological plausibility refers to does an
15 association make sense? Is there some plausible
16 pathway through which exposure to these products can
17 cause cancer?

18 Q. Is biological plausibility the same as
19 biological proof and biological certainty?

20 A. No, it is not.

21 Q. Why not?

22 A. Biological plausibility the guideline is just
23 that if you determine a way in which this could
24 happen, that is sufficient to determine that a cause
25 could happen.

1 Q. Based on the biology or science?

2 A. This recognizes biology is a moving field. At
3 one point we may understand more biology than what we
4 do at other points.

5 Q. Dr. McTiernan, do you have an opinion whether it
6 is biologically plausible for talcum powder products
7 to cause ovarian cancer?

8 A. Yes, I do.

9 Q. What are those opinions?

10 A. I believe talcum powder products, first of all,
11 contains known carcinogens, and there is a list of
12 them here, and IARC has been very clear that asbestos
13 causes ovarian cancer. These several components or
14 constituents of talcum powder products are known
15 carcinogens, are classified as such by IARC, and these
16 constituents have been shown through various
17 laboratory studies and laboratory testing to be in
18 these products.

19 THE COURT: Dr. McTiernan, you started by
20 saying, talking about known carcinogens, and you
21 mentioned the asbestos specifically. Would your
22 opinion change if there was not asbestos in the talc?

23 THE WITNESS: It wouldn't change because the
24 epidemiologic studies only asked about talcum powder
25 products. They weren't able to ask the women, did you

1 use asbestos? That is all from the product itself,
2 talcum powder product.

3 BY MS. PARFITT:

4 Q. Dr. McTiernan, did you review any documents in
5 preparation for the opinions with regard to the
6 components of talcum powder products, just briefly?

7 A. I did. I reviewed some published literature. I
8 reviewed some testing documents that were provided to
9 me by you and your colleagues showing that internal
10 testing by J&J and testing by Dr. Longo.

11 MR. WILLIAMS: Objection to this line of
12 questioning concerning the J&J documents for purpose
13 of this hearing.

14 MS. PARFITT: It was foundational, how she
15 finished forming her opinions --

16 THE COURT: I'll let her talk about what she
17 reviewed without getting into the documents.

18 BY MS. PARFITT:

19 Q. Did you review internal J&J testing documents?

20 A. Yes.

21 Q. Did you also review testing documents by
22 Dr. Longo?

23 A. Yes.

24 Q. Did you also review testing documents published
25 in the peer-reviewed literature?

1 A. Yes.

2 Q. And you reviewed IARC?

3 A. I did.

4 Q. Having reviewed that information, did you
5 satisfy yourself that talcum powder products that
6 Johnson & Johnson manufactured may contain these
7 component parts, these carcinogens?

8 A. Yes.

9 Q. For purposes of your opinion in this case, have
10 you made -- do you have the understanding that the
11 talcum powder products includes whatever is in the
12 talcum powder products, whether that be asbestos,
13 heavy metal and fragrance?

14 A. Yes.

15 Q. What is your next opinion?

16 A. First, that the exposure that talcum powder
17 products can reach the Fallopian tubes and ovaries, it
18 is an open system and there is evidence that genital
19 application can migrate up through the genital tract.
20 We know from -- and in addition, these substances can
21 be inhaled and spread through the lymphatic system and
22 circulatory system.

23 Q. What are the two pathways?

24 A. Genital application and inhalation. There has
25 been scientific clinical studies showing in humans --

1 we'll talk about migration -- that several clinical
2 studies in humans show that application of particles
3 of similar size to talc when applied to the genital
4 tract can move up to the Fallopian tubes and ovaries.
5 I keep saying "Fallopian tubes," which is relevant
6 because some ovarian cancers start in the Fallopian
7 tubes and then move up to the ovaries, so both
8 Fallopian tubes and ovaries are relevant.

9 So the substances have been applied either --
10 the substances themselves or a radioactive substance
11 or powder on gloves, and these were all when women
12 were about to have surgery, these substances were
13 applied; and when the women had surgery, hours or days
14 later the substances had migrated up.

15 Q. Does that include talc particles as well?

16 A. We know that talc is present in ovaries. It was
17 shown to be present in several ovaries, and it was
18 shown to be present in lymph nodes, in the area around
19 the ovaries. We know that in one study found that
20 after correcting for the surface contamination,
21 possibly in lymph nodes in that area, that inside the
22 lymph node there was talc, and it was highly
23 correlated with whether the woman reported use of
24 talc, that was McDonnell 2006 I listed there.

25 Q. That's pathology?

1 A. Pathology and clinical because the women
2 reported their use or not. Yes, so talc is present
3 there. It is in there. The studies have shown that
4 substances can migrate.

5 The reasons the studies were not able to apply
6 talc and see if that migrates, it wouldn't be ethical
7 to do that. They chose other substances, and many of
8 those were fertility type of studies. They were able
9 to do those tests and see what happens.

10 The regulatory bodies also state that
11 migration is a plausible method for the substance
12 talcum powder product to reach the ovaries and
13 Fallopian tube, and the FDA stated it is
14 incontrovertible that it can migrate.

15 The next step I considered is what is a
16 possible pathway for carcinogenesis, and one I'm
17 interested in that I think is plausible is
18 inflammation. We know from clinical studies that talc
19 when injected into the human body causes inflammation.
20 So there is a medical use of talc called. It's called
21 a pleurodesis study. This is for two types of
22 patients that develop air around their lung. It's
23 called pneumothorax. Some of those patients have
24 spontaneous pneumothorax and some have it because they
25 have a serious disease. When talc is injected into

1 that area it causes inflammation that causes
2 adhesions, and that's why it is used as a one-time
3 treatment. That inflammation shows up in the blood
4 within hours. So we know that talc causes
5 inflammation. Numerous animal studies show
6 inflammation and carcinogenic processes consistent
7 with carcinogenesis.

8 We know cell culture studies have shown that
9 talc applied can cause changes to cells that change
10 the genetics. We call it epigenetics. That can make
11 those changes that are premalignant and then can lead
12 to carcinogenesis.

13 Q. You said epigenetics.

14 A. Epigenetics. Cancers of genetic disease, but
15 only about 10 percent of cancers are caused by genes
16 you inherit from your parents.

17 Other genetic causes are environment, and
18 talcum powder products is one environmental cause that
19 can affect the cell's genome and cause cancer that
20 way.

21 Q. Any other credible scientific evidence that you
22 reviewed generally to support your opinion talc causes
23 an inflammatory pro-carcinogenic biologic effect in
24 the body?

25 A. Yes. We know from the in vitro and animal

1 studies that that can happen, and we know women who
2 have high inflammation in the blood have increased
3 risk for ovarian cancer. Many of these cohort studies
4 have shown that. We know women with inflammatory
5 conditions -- endometriosis, pelvic inflammatory
6 disease have increased risk.

7 Q. Dr. McTiernan, have you included on your
8 demonstrative some of the studies that support both
9 pathologic studies, clinical studies, animal studies,
10 and in vitro studies to support this cascade of
11 events?

12 A. Yes.

13 Q. At the end of that, what happens?

14 A. At the end of that, after inflammatory response
15 --

16 Q. What is the role of inflammation on oxidative
17 stress, those things you have spoken about in the
18 pathogenesis of cancer?

19 A. Inflammation, the process of that can cause
20 oxidative stress that then can cause genetic damage
21 and then cause cancer.

22 MS. PARFITT: Dr. McTiernan -- and for the
23 Court, I made a misstatement on my McDonald. I have
24 2006. That should be McDonald 2019.

25 (Pause.)

1 MR. WILLIAMS: Our objection, your Honor, is
2 that the McDonnell study was one that was discussed
3 expressly with the Court in chambers on a couple of
4 occasions. It was listed on two other witnesses'
5 supplemental lists but not on Dr. McTiernan's list.
6 It was not referenced in her original report either.
7 Our objection is, for purposes of Dr. McTiernan's
8 testimony, it is not appropriate based on the Court's
9 previous ruling for her to testify concerning it.

10 THE COURT: Was it on her supplemental list?

11 MS. PARFITT: Yes. It says "all briefing."

12 THE COURT: No, no, no. Did she list that
13 particular study on a supplemental list?

14 MS. PARFITT: No, we did not. We listed it
15 with the briefing. It came out after her report,
16 after her testimony.

17 THE COURT: I think you had some very specific
18 things listed and it is not there.

19 MS. PARFITT: Because it was in the briefing
20 we didn't do that. So we could move on.

21 THE COURT: Let's move on. Even though you
22 did it in the context of correcting the data on the
23 McDonald study, but we will not be discussing the
24 McDonald study as something you relied on.

25 BY MS. PARFITT:

1 Q. Dr. McTiernan, do your opinions change with
2 regard to whether or not it is biologically plausible
3 for talcum powder products to cause ovarian cancer if
4 you did not consider the McDonald study?

5 A. My opinions don't change at all, and my expert
6 report was completed before that paper was published.

7 Q. Thank you.

8 Let's move on to the next.

9 THE COURT: Did you complete your questioning?
10 I want to make sure where you were. You got
11 interrupted about the date of the report. I want to
12 make sure.

13 Q. What role does inflammation and oxidative stress
14 have in the pathogenesis of ovarian cancer?

15 A. Oxidative stress, it starts a cascade of DNA
16 damage, and it is one explanation through which
17 inflammation can cause ovarian cancer.

18 Q. Dr. McTiernan, in the course of your review and
19 study and opinions, did you also consider studies that
20 perhaps disagreed with your opinion with regard to
21 whether or not talcum powder products can cause
22 ovarian cancer?

23 A. Yes.

24 Q. Did you take that into consideration in
25 rendering your opinions?

1 A. Yes.

2 Q. Moving on to the next aspect of Bradford Hill,
3 and that would be dose-response, otherwise known as
4 biological gradient. What is dose-response?

5 A. Dose-response is the question of whether the
6 increase in use of some product or increasing exposure
7 is associated with a change in level of relative risk.
8 In this case, our question was: Does increasing use
9 of talcum powder products increase risk of ovarian
10 cancer?

11 One study that was able to look at this,
12 because they had such large numbers, was the Terry
13 study. We'll use that as an example of dose-response.

14 One way to do dose-response is among people
15 who are using the product, to divide them into
16 categories, and then look across those categories,
17 compared to never users, what is the relative risk of
18 ovarian cancer in each of those categories.

19 Q. Before you do that, what's the optimal metric if
20 there is one for dose-response?

21 A. Relative risk in epidemiological studies, we
22 look at relative risk. And so in the Terry study,
23 they divided women into four categories by level of
24 use of talcum powder products, and compared to never
25 users. On this table, the letters "OR" stands for

1 odds ratio, and that's the same thing as relative
2 risk.

3 So what they are able to see, those women who
4 had never used. The number there is 1. That means
5 they are the comparison group. When you see -- when
6 you look across the quartiles, that's --

7 Q. Do you have a pointer?

8 A. -- increasing level of use, and he's outlined it
9 nicely, you see the relative risk for the first
10 category is 1.14; for the second, 1.23; the third,
11 1.22; and the fourth, 1.32. This is risk of any
12 ovarian cancer by level of use.

13 You see that the level goes up. 1.14 is
14 higher than 1.1, 1.23 to 2, are higher than the first
15 category, and the highest is the top category.

16 The authors' calculated confidence intervals
17 for each of those levels of relative risk, and they
18 all show significance or near significance meaning
19 they don't include 1. The first category does, and
20 that's why it is often called "near significant."
21 That's how some people would describe that.

22 And then there is another statistical tool
23 that is often used in dose-response to calculate how
24 likely this trend would be -- sorry. It tells us how
25 correct we are by rejecting a hypothesis, that there

1 is no dose-response. So these would be p-Values.

2 They calculated p-Values in two different ways. This
3 is called the p-Trend, and they included one of them
4 here in the table, but they put one in the text.

5 Q. What is the significance of that?

6 A. What this one is, p-Trend, this is looking only
7 at the people who used talcum powder products, just
8 comparing those four categories, and that trend is
9 .17. What that means is that they are estimating that
10 17 times out of 100 you would make an error by
11 assuming there was a dose-response when there really
12 isn't.

13 I'm about to talk about the other p-Trend
14 which they describe in the text. If you compare those
15 categories to the non-users, the p-Value is less than
16 .01. That means it would be less than 1 time out of
17 100 that you would make a mistake by saying that there
18 was a trend when there really wasn't.

19 So three different ways of using a statistical
20 tool to help you interpret them. I interpret this as
21 showing dose-response. It shows the relative risk
22 confidence intervals that were narrow -- that weren't
23 terribly wide and did not include one. The
24 statistical test compared to non-users was highly
25 significant although the statistical test comparing

1 only users was not.

2 Q. Dr. McTiernan, would it be inappropriate
3 methodology to include never users in that assessment?

4 A. I believe it is appropriate to include the never
5 users. First of all, the statisticians advise that we
6 do include non-users. But it would be comparable to,
7 in a clinical trial, if you wanted to look at what
8 effect different doses of a medicine would have you'd
9 randomly assign people to different doses and to a
10 placebo, and then you compare those different doses to
11 placebo. That's kind of what we do in epidemiology,
12 comparing it to a placebo, to people without the
13 exposure.

14 So I believe it is correct to compare to that
15 and in my studies I usually do. But I think it is
16 very correct as they did to show all of this so that
17 different investigators can see the data fully. So I
18 think it's appropriate they presented two different
19 p-Values and that they showed confidence intervals.

20 Q. Dr. McTiernan, is there a threshold response the
21 public would expect?

22 A. A threshold of what, relative risk?

23 Q. A threshold of relative risk.

24 A. No, there is no particular one, and there are
25 different shapes a dose-response can have. Some can

1 be a straight arrow -- I'm sorry. Straight up, one
2 dose increases a certain amount. It could be like
3 this one is, where it just shows that you see an
4 increase at the first level, and the second and third
5 look very similar, and the top level looks the
6 highest. Some exposures have a curve, a U-shaped
7 curve. So there are different types of things an
8 exposure can do in terms of dose-response.

9 In this one I interpret, because the highest
10 relative risk was in the highest dose, and you see
11 some step-wise increase, to me it really looks like
12 there is a dose-response.

13 Q. Dr. McTiernan, do you have an opinion whether a
14 single dose of talcum powder can cause ovarian cancer?

15 A. I think we don't know what a dose could cause.
16 If one piece of one application of talc got into the
17 ovaries or Fallopian tubes and sat in there and caused
18 an inflammation and continued because talc is unlikely
19 to be able to be rinsed away from the body, if it
20 continues in there and continues to cause
21 inflammation, perhaps. But with more applications,
22 you have an idea there is more chance of the substance
23 being incorporated into the body, and therefore could
24 set up inflammation and other methods of causing
25 cancer.

1 Q. Is there any other example? Were there any
2 other studies that categorized the dose-response?

3 A. Yes, two other meta-analyses. The large
4 meta-analysis were able to do that, and this is data
5 from individual studies.

6 So this one is from one of the recent
7 meta-analysis Penninkilampi, and they were able to
8 find most studies that had some information either on
9 duration of use or total lifetime applications. When
10 they looked at the 12 studies who had duration of use,
11 they looked at for those women who used for more than
12 10 years compared to less use, the relative risk was
13 1.25. So that tells us long-term use has an effect.
14 Five of those studies they included the meta-analysis
15 had total lifetime applications. So it's frequency
16 times duration. And they divided those into two
17 categories corresponding to daily use for 10 years.
18 So 3600 total applications more or less, and you did
19 see an increase. You see a relative risk of 1.32 for
20 the lower group users and 1.42 for the higher, and
21 this is compared to non-users. The confidence
22 intervals did not include one, so they are
23 statistically significant.

24 Q. Is there another way of categorizing
25 dose-response other than classifying these core files

1 and frequency duration?

2 A. Another thing researchers often do is modeling,
3 and they will take all the information and do some
4 statistical models to smooth out curves and get an
5 estimate of where the risk increases with increasing,
6 in this case, either duration or frequency. So the
7 Berge study meta-analysis looks at the studies that
8 had duration, and what they are modeling, they were
9 able to estimate that the relative risk was 1.16 for
10 each 10 years of use, also statistically significant.
11 And for the studies that had frequency for each one
12 dose per week, used one time per week, a relative risk
13 of 1.05, a 5 percent increase, also statistically
14 significant.

15 So this tells me there is a dose-response
16 effect looking across these different ways of doing
17 it, and that it is consistent across studies -- sorry.
18 I was about to say something else, but I forgot.

19 Q. Dr. McTiernan, you talked about these studies
20 that demonstrated an increased dose-response with
21 increasing use and duration. Does Bradford Hill
22 require there be a finding of dose-response?

23 A. No, it does not.

24 Q. And based upon the totality of your review of
25 the studies, let me ask you this: Did you look at

1 studies that did not look at dose-response?

2 A. I did. Some studies didn't look at
3 dose-response. Some looked at only frequency or
4 duration, not both. Some looked at dose-response and
5 found no effect, and some looked at it and found
6 effect.

7 Q. Based upon the totality of your review of those
8 studies that looked at dose-response, didn't look at
9 dose-response, or looked at dose-response and couldn't
10 find it, what is your opinion?

11 A. Looking over all, there is a dose-response
12 particularly because the meta-analysis and the pooled
13 analysis saw that clearly.

14 Q. What I'm going to do, to shorten this, is put up
15 a slide that you helped me prepare. It is the
16 Bradford Hill guidelines. We talked about strength
17 consistency, dose-response, and biological
18 plausibility. What I would like you to do is briefly
19 go through the remaining, and then, in the interest of
20 time, tell us why you've got a weight category over
21 there.

22 MR. WILLIAMS: Your Honor, we are mindful of
23 the time. I don't see counsel cutting anything
24 actually.

25 THE COURT: I think we are in major summary

1 stage right now.

2 BY MS. PARFITT:

3 Q. Let me ask you this: Did you consider the
4 remaining Bradford Hill considerations?

5 A. I did.

6 Q. What was the process you went after evaluating
7 the Bradford Hill guidelines?

8 A. After review, I determined that I gave high or
9 significant weight to strength, consistency,
10 dose-response, plausibility, and temporality. I gave
11 moderate weight to specificity and slight weight to
12 experiment; and for both coherency and analogy in my
13 opinion, I weighed it less than strength and
14 consistency.

15 Q. Did the evidence you reviewed satisfy the
16 coherence category?

17 A. Yes.

18 Q. Did the evidence you reviewed satisfy
19 temporality aspect?

20 A. Yes.

21 Q. Did the evidence you reviewed satisfy the
22 specificity?

23 A. Yes.

24 Q. Did the evidence you reviewed satisfy the
25 analogy?

1 A. Yes.

2 Q. And you talked about the experiment.

3 Dr. McTiernan, in addition to the opinions
4 that you've shared with us today, are the opinions you
5 shared your opinions?

6 A. Yes.

7 Q. Did you consider opinions and recommendations of
8 other scientific and regulatory bodies who also opined
9 on the issue of whether or not talcum powder causes
10 ovarian cancer?

11 A. Yes.

12 Q. Did you learn anything from them?

13 A. I was very interested to learn that some other
14 regulatory bodies found similar findings that I did,
15 such as Health Canada.

16 Q. Were there regulatory bodies that have not
17 opined in the same way as you?

18 A. There were some, yes, but they did not do a full
19 systematic review and a full causal analysis.

20 MR. WILLIAMS: Objection. Foundation, your
21 Honor.

22 THE COURT: Sustained.

23 BY MS. PARFITT:

24 Q. Dr. McTiernan, did you review other opinions of
25 scientific and medical and regulatory agencies on the

1 issue of talcum powder products?

2 A. I did, yes.

3 Q. Other than just Health Canada?

4 A. I did, yes.

5 Q. Which ones did you look at generally?

6 A. IARC has looked at this in more detail, and they
7 have done a systematic review, but it was in 2006.

8 I've noted IARC plans to relook at talcum
9 powder product use and risk of ovarian cancer. They
10 placed it in high priority. At the time they reviewed
11 it, they only had data up until 2006, but they did a
12 full review. So they classified talcum powders as
13 Class II B carcinogen.

14 Q. Have you addressed in your report and in your
15 testimony by deposition some of the other regulatory
16 and scientific bodies that have also examined this
17 issue?

18 A. I've looked into some of them, yes.

19 Q. And you have taken that into consideration in
20 rendering your opinions?

21 A. Yes.

22 Q. Dr. McTiernan, summarize for us, interval, what
23 your opinions are today.

24 A. My opinions are published studies --

25 MR. WILLIAMS: I object. These have already

1 been covered.

2 THE COURT: Yes. I looked back -- I think
3 it's your last slide, and every one of these has been
4 in her testimony. If you think there is one that is
5 not, you could ask her specifically.

6 MS. PARFITT: I think you are correct, your
7 Honor.

8 THE COURT: I think they have all been
9 covered. She's already indicated she helped create
10 these slides. I understand she's adopting what I'm
11 seeing up there -- am I correct -- as your opinions?

12 THE WITNESS: Yes.

13 MS. PARFITT: Your Honor, at this time I would
14 conclude my examination. And I appreciate your
15 courtesy with regard to the time.

16 THE COURT: We'll break for lunch. It is
17 12:15. 1 o'clock.

18 THE DEPUTY CLERK: All rise.

19 (The luncheon recess is taken.)

20 (Continued on the next page.)

21 ///

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A F T E R N O O N S E S S I O N

THE DEPUTY CLERK: All rise.

THE COURT: Thank you.

Anne McTiernan resumed.

CROSS-EXAMINATION

BY MR. WILLIAMS:

Q. Good afternoon, Dr. McTiernan.

A. Good afternoon.

Q. We have met before, have we not?

A. Yes.

Q. Let me ask you again to try to keep your voice up.

A. Okay.

Q. Dr. McTiernan, you were retained in this litigation to review the current state of scientific literature regarding talcum powder products and opine on whether those products cause ovarian cancer. True?

A. True.

Q. The reference to talcum powder products in your litigation report refers to commercially available talcum powder products and all constituent elements

1 contained therein. Correct?

2 A. Yes.

3 Q. Asbestos is an example of a constituent element
4 that in your opinion may be contained within talcum
5 powder products. Correct?

6 A. Yes.

7 Q. You are not an expert in asbestos, though.
8 Right?

9 A. Asbestos, in which way?

10 Q. In the determination of whether a product --
11 yes, a product contains asbestos in the first
12 instance?

13 A. In terms of testing?

14 Q. That's right.

15 A. Correct.

16 Q. You are not an expert?

17 A. Correct.

18 Q. For that issue you are relying on others.
19 Correct?

20 A. Yes.

21 Q. You did not do a full systematic search for
22 causal analysis for asbestos?

23 A. Correct. I was not asked to do that.

24 Q. To be clear, though, your opinion is that talcum
25 powder products can cause ovarian cancer even if those

1 products do not contain asbestos or any other
2 constituent element besides talc. True?

3 A. True.

4 Q. You were first approached about any involvement
5 in talcum powder litigation in 2016. Right?

6 A. I would have to refresh my memory for the exact
7 dates. I don't have them right with me. I can get
8 them, but I don't have them.

9 Q. Let me see if I can refresh your memory, and I
10 should have begun by saying there are two binders in
11 front of you, binder 1 and binder 2, and there should
12 also be a red binder as well. Do you have that one?

13 A. Yes.

14 Q. That red binder should have your previous
15 testimony.

16 (Pause.)

17 Do you have the red binder in front of you,
18 Dr. McTiernan?

19 A. Yes.

20 Q. I'll direct your attention to page 12.

21 MR. WILLIAMS: Permission to read, your Honor,
22 lines 12 through 15.

23 THE COURT: Yes.

24 Q. (Reading.)

25 "QUESTION: Dr. McTiernan, when were you first

1 approached about any involvement in talcum powder
2 litigation?

3 "ANSWER: It should have been 2016."

4 Does that refresh your memory, it was in fact
5 2016 when you were first approached?

6 A. I remember saying that, yes.

7 Q. And you would not have said that were it not
8 true. Correct?

9 A. Correct. But even at that time I didn't have
10 the exact dates. I didn't have documentation. It was
11 from my memory then and it is now.

12 Q. You have not personally conducted any research
13 on talcum powder use and risk for ovarian cancer as of
14 the time you were retained by plaintiffs' counsel.
15 Correct?

16 A. I had read some papers prior to that. I read
17 two cohort studies and pooled analysis, and because my
18 university is where some of the early case-control
19 studies occurred, I was aware of those, but I did not
20 do a systematic review until after I was retained.

21 Q. I would like you to focus on my question.

22 You had not personally conducted any research
23 on talcum powder use and risk for ovarian cancer as of
24 the time you were retained. Correct?

25 A. I think I was understanding the word "research"

1 to mean read into it. If you mean research conducting
2 the studies, no, I did not.

3 Q. At the end of your testimony on direct
4 examination, counsel took you through this chart; and
5 at the end of the chart or on the right-hand side,
6 there was a discussion about biological plausibility
7 and, in particular, inflammation carcinogenesis.
8 Right?

9 A. Yes.

10 Q. And you listed here with the assistance of
11 counsel the basis for your opinion regarding
12 biological plausibility. Correct?

13 A. Yes.

14 Q. The first thing you listed was clinical studies
15 and pleurodesis studies. Right?

16 A. Yes.

17 Q. Have you looked into the studies that relate to
18 whether or not there is a relationship between
19 pleurodesis -- that is, the intentional injection of
20 talcum powder into the chest cavity for lungs and the
21 impact on cells?

22 A. I think in my -- I think in my documents in my
23 report I cited to research in this area showing that
24 pleurodesis causes an inflammatory response.

25 Q. Other than causing an inflammatory response, any

1 discussion that you are aware of or studies you are
2 aware of as to the impact on human cells of talc being
3 applied to them?

4 A. I think I want to look at my report and see what
5 I said about pleurodesis.

6 Q. Take a look in your book. In the first notebook
7 it is Exhibit McTiernan 5-09, actually, the second
8 volume, Volume 2, and it is McTiernan 509.

9 (Pause.)

10 Have you ever seen this study before, Doctor?

11 A. I don't believe I have.

12 Q. This study you will see it is called the Nasreen
13 study. It is from the year 2000, and I'll direct your
14 attention to the very beginning of the tab it says:

15 "Pleurodesis with talc is an accepted method
16 for the treatment of systematic pleural effusions
17 secondary to mesotheliomas."

18 Do you see that?

19 A. Yes.

20 Q. I want to direct your attention a few lines down
21 it says:

22 "The present study was designed to evaluate if
23 talc directly affects cell death of malignant
24 mesothelioma cells or normal pleural mesothelial cells
25 PMC."

1 You are familiar with the process of
2 pleurodesis?

3 A. Yes.

4 Q. Let's go to the bottom, the part we highlighted
5 down below. It says:

6 "Talc did not induce apoptosis."

7 You understand, by the way, apoptosis is
8 planned cell death?

9 A. Yes.

10 Q. (Reading.)

11 "Talc did not induce apoptosis in PMC," and
12 those are the mesothelial cells.

13 A. Pleural mesothelioma cells, that's what it
14 states.

15 Q. That's what it referred to the PMC?

16 A. Yes.

17 Q. (Reading.)

18 "And glass beads did not cause significant
19 apoptosis in either MNC or PMC."

20 "The present study has demonstrated that talc
21 induces apoptosis in MMC without affecting normal
22 mesothelial cells of the pleura."

23 Did I read that right?

24 A. Yes.

25 Q. Let me ask you to turn to page 5 of Exhibit 509,

1 the conclusion, and direct your attention to the left
2 column at the very bottom.

3 Do you have that in front of you?

4 The Nasreen authors concluded:

5 "In conclusion, the significance of this study
6 is that talc induces apoptosis in MMC without
7 affecting normal pleural mesothelial cells. These
8 findings also demonstrate that talc, a palliative
9 active agent, may have a therapeutic potential in
10 decreasing tumor burden. Therefore, it may be
11 construed that talc not only induces pleurodesis, but
12 also decreases the size and mass of tumors in patients
13 with mesothelials."

14 Did I read that right?

15 A. Yes.

16 Q. Can you point the Court to any study that
17 suggests with respect to ovarian cells that talc
18 induces cellular proliferation -- strike that.

19 Can you point the Court to any study that was
20 part of your analysis that suggests when talc when
21 applied to ovarian causes harm to those cells leading
22 to malignancy?

23 A. I think in my report I referred to Buz'Zard
24 which showed that talc applied to human ovarian
25 stromal and epithelial calls resulted in increased

1 reactive oxygen species, cell proliferation, the
2 excessive growth of cells, and neoplastic
3 transformation of cells. So ovarian cells, not
4 pleural cells.

5 Q. Any other study besides Buz'Zard for that
6 purpose cited in your report?

7 A. That's what I have here, yes.

8 Q. Let's take a look at it. It is Exhibit A 16 and
9 in your book it should be Volume 1.

10 MR. WILLIAMS: Your Honor, in your book it
11 should be Volume 1 as well.

12 Q. Let me start with, first, principles.

13 The presence of oxidative stress in tissue
14 does not indicate that cancer will develop. True?

15 A. Oxidative stress is a risk factor for cancer.

16 Q. The presence of oxidative stress in tissue does
17 not indicate that cancer will develop in that tissue.
18 True or not true?

19 A. My opinion is that oxidative stress increases
20 risk for cancer. So it is something we've looked at
21 as potentially part of carcinogenesis.

22 Q. Any oxidative stress?

23 A. There are many aspects to oxidative stress and
24 many parts of the cascade. My understanding is that
25 increased oxidative stress is a risk factor for

1 carcinogenesis.

2 Q. Do you remember the Buz'Zard study was to assess
3 the effects of a supplement made from modified French
4 maritime pine bark?

5 A. Yes.

6 Q. Have you advised anyone to start using the
7 product related to this study which is entitled
8 Pycnogenol? See if that is referenced in the title of
9 the article.

10 Have you advised anyone to start using
11 pycnogenol for ovarian cancer?

12 A. No.

13 Q. The ovarian cells used in the French pine bark
14 study were genetically altered?

15 A. Could you point to where that says that?

16 Q. Let me ask you to assume the Buz'Zard study used
17 genetically altered ovarian cells that did not have a
18 p53 protein. Can you make that assumption with me?

19 A. I don't like making assumptions when we are
20 talking about scientific papers. If you can show me
21 where it says they were not genetically altered, that
22 would help.

23 Q. In court we are permitted to ask hypothetical
24 questions, so I would like to ask you one based on
25 your scientific knowledge separate and apart from the

1 study itself.

2 Would you assume with the Buz'Zard study used
3 genetically altered ovarian cells that did not have a
4 p53 protein? Are you with me?

5 A. I'm with you. As a scientist, I don't make
6 assumptions like that. I'm finding it difficult. You
7 are trying to ask me a scientific question.

8 Q. I am.

9 A. I'm having trouble making assumptions for
10 something where I don't know what kind of cells they
11 used in the study.

12 Q. You cited the Buz'Zard study for the proposition
13 that it showed reactive oxygen species increased if
14 talc was applied to cells. Correct?

15 A. Yes.

16 Q. Let me direct your attention -- strike that.

17 The Buz'Zard study showed that the reactive
18 oxygen species actually decreased from baseline the
19 more talc was applied. Do you remember that?

20 A. I believe that was a temporary decrease, and
21 then it increased. I would like to look at the
22 relevant graph.

23 Q. It is on page 5 of Exhibit A 16. I will direct
24 your attention to the top graph there. This chart
25 reflects the author's findings on "Generation of

1 Reactive Oxygen Species From Ovarian Epithelial in
2 Response to Their Exposure to Talc." Correct?

3 A. This is the study where if you look under the
4 graph, the authors are explaining it more, that there
5 was an initial dose dependent decrease, but as time
6 increased the ROS generation rebounded and increased
7 compared with values at 24 hours.

8 Q. Let's take a look at the graph.

9 You see 100 is the baseline, right, and the
10 unit of measurement is the percentage of ROS
11 generation. Right?

12 Do you see that on the Y axis?

13 A. Can you explain where you are seeing 100 is the
14 baseline?

15 Q. Are you saying there was something else that was
16 the baseline?

17 A. Just to explain what the graph is meaning.

18 Q. I'll represent to you there has been testimony
19 concerning this graph, and I'll just ask you this:

20 Do you see as more talc is applied, and we
21 move to the right along the X axis, that the bar
22 charts go below the 100 line except for this one which
23 was at 50 micrograms per milliliter. Can we agree on
24 that?

25 A. Yes, I see that. I'm wondering why the authors

1 wrote that was a temporary decrease and this
2 increased.

3 Q. Perhaps could it have been because as each of
4 these bars for any one segment was 424, 72 and
5 120 hours, and in any given time period it did
6 increase. Do you see from 24 to 72 to 120 hours?
7 Could it be that is what they were referring to?

8 A. I'm not sure. I'm just reading the writing it
9 increased over time.

10 Q. What we do know is all of these except for one
11 is below the baseline. You can agree on that?

12 A. It looks like a temporary change from what they
13 wrote.

14 Q. Are you speculating?

15 A. They said it was an initial dose-dependent
16 decrease, and then that increased. That's why I'm
17 confused. It looks like the graph and the description
18 are showing -- the description is showing additional
19 information.

20 Q. That's fine. We'll move on.

21 The next studies you talked about were the
22 animal studies, and you list three. Correct?

23 A. Yes.

24 Q. And you list these as studies that supposedly
25 support the notion that there is biological

1 plausibility that flows from talcum powder product use
2 to exposure to migration, to inflammation and
3 carcinogenesis. That's why you cited them?

4 A. I cited them as looking at the pieces of the
5 carcinogenic pathway. This is one issue we see with
6 looking at this biological plausibility. We have
7 different pieces of information along the chain of
8 possible biological mechanisms.

9 Q. I assume you cited these not because they are
10 the worst studies you could cite, but they were the
11 strongest studies supporting your position for your
12 conclusion as a scientist?

13 A. I didn't do a systematic review on biological
14 plausibility on animal studies. What I did was I
15 looked for animal studies that possibly could explain
16 the association, and I did that with either PubMed
17 search or looking at references that were referenced
18 in epidemiological studies and the clinical studies.

19 Q. You did read the studies, right?

20 Let's take a look at Keskin. It is Exhibit A
21 85.

22 A. Yes.

23 Q. Exhibit A 85 is the 2009 study by Keskin that
24 you were just referencing. Right?

25 A. Yes.

1 Q. It's entitled, "Does long-term talc exposure
2 have a carcinogenic effect on the female genital
3 system of rats."

4 Did I read that right?

5 A. Yes.

6 Q. Do you remember in this study the researchers
7 applied talc to rats intra-vaginally or perineally for
8 three months on a daily basis?

9 A. I see that.

10 Q. Let's go to the findings.

11 Page 2, second column, second paragraph, first
12 sentence. Finding:

13 "In both the groups exposed to talc, Groups
14 III and IV, evidence of foreign body reaction and
15 infection along with an increase in inflammatory cells
16 were found in all the genital tissues. General
17 infection was observed in 12 rats in the study group
18 and two rats in the control group. Neoplastic change
19 was not found."

20 This study found that there was no neoplastic
21 change in the rats who had the talc directly placed
22 into their ovaries. Correct?

23 A. Yes.

24 Q. The next study that you referred to on your
25 chart is the Hamilton study from 1984. Did you read

1 that study?

2 A. Can we go back to the former study Keskin?

3 Q. Counsel will take you back if she wishes.

4 The Hamilton study is Exhibit A 53, which
5 should be in your first volume, Dr. McTiernan. In
6 this study the authors surgically injected talcum
7 powder into the ovarian bursal sac of rats. Right?

8 A. Yes.

9 Q. It was not the case that talc was applied to the
10 outside or the exterior of the rats' genital area.
11 Correct? The talc was injected into the ovaries
12 themselves. You remember that. Right?

13 A. Yes.

14 Q. The researchers injected the talc into 10 rats.
15 Right?

16 A. This is what the abstract says, yes.

17 Q. And out of the 10 rats injected with talc, four
18 of them -- less than half -- showed some kind of
19 papillary change in the ovarian surface epithelium.
20 Is that right, Doctor?

21 A. Yes.

22 Q. The authors concluded, though, that the
23 epithelium covering the papillary areas was regular
24 with no evidence of cytoplasmic or nuclear atypia.
25 Correct? That's on page 4 of the exhibit, right

1 column, in the carry over paragraph midway down. That
2 was the conclusion of the study?

3 A. Four of them developed papillary areas and
4 "papillary" means abnormal growth.

5 Q. But any chronic inflammation that the Hamilton
6 study authors observed in the rats did not lead to
7 neoplastic changes?

8 A. They are talking about papillary areas, again,
9 which is abnormal growth.

10 Q. We were just reading the portion that said it
11 did not lead to neoplastic changes --

12 A. Could we see the abstract again.

13 Q. It is the next one.

14 A. Back to the abstract. I'm trying to read the
15 abstract. This says something about this there.

16 Q. Sure.

17 (Pause.)

18 A. I don't see here in the abstract they are
19 concluding they are not related. I see papillary
20 changes. From my knowledge, "papillary" is an
21 abnormal growth, and papillary growth could be the
22 beginning of a carcinogenic process.

23 Q. Are you speculating?

24 A. I'm talking about my knowledge, and they talk of
25 four of 10 animals developing papillary changes.

1 Q. Let's move on. The next study you cited in
2 support of biological plausibility opinion in the case
3 was the NTP study from 1993. Do you remember that?

4 A. Yes, I do.

5 Q. Now, you mentioned earlier today that there was
6 an agency that had found that talc could migrate from
7 the perineum to the ovaries. Do you remember
8 testifying to that earlier today?

9 Do you remember testifying to that today?

10 A. Yes, I stated the FDA said migration was
11 incontrovertible.

12 Q. You based that on a letter you read at one
13 point?

14 A. Yes.

15 Q. Let's put that in front of you. That's Exhibit
16 A 89.

17 MR. WILLIAMS: Your Honor, for the record, it
18 is a letter dated April 1, 2014.

19 Q. Is that the letter?

20 A. I see it, yes.

21 Q. Now, in this letter do you remember there was a
22 specific discussion of the NTP report?

23 A. Maybe we could scroll to it or point to it in
24 the book.

25 Q. It is on page 4 of the letter under toxicology

1 findings. Do you see that heading?

2 A. Yes.

3 Q. There is a reference here that speaks of the NTP
4 report concluding that cosmetic grade talc caused
5 tumors in animals even though no asbestos-like fibers
6 were found. The report made the following
7 observation:

8 "There was some evidence of carcinogenetic
9 activity in non-asbestiform talc from inhalation
10 studies in male rats based on an increased incidence
11 of benign or malignant pheochromocytomas of the
12 adrenal gland. There was clear evidence of
13 carcinogenic activity of talc in female rats based on
14 increased incidences of alveolar/bronchiolar adenomas
15 and carcinomas of the lung and benign or malignant
16 pheochromocytomas of the adrenal gland. There was no
17 evidence of carcinogenic activity of talc in male or
18 female mice exposed to 6 or 18 micrograms per cubic
19 meter. However, this study lacks convincing
20 scientific support because of serious flaws in its
21 design and conduct including the investigators used
22 micronized talc instead of consumer grade talc
23 resulting in the experimental protocol not being
24 reflective of human exposure conditions in terms of
25 particle size."

1 Do you remember reading that in the FDA letter
2 regarding the NTP study upon which you rely?

3 A. I see it now.

4 Q. Let's go to the next page.

5 Do you remember the FDA letter upon which you
6 relied said:

7 "Investigators conceded that they had problems
8 with the aerosol generation system; whereby, the
9 target aerosol concentrations were either excessive or
10 not maintained during 26 of the 113 or 122 weeks of
11 the study. The study did not include positive and
12 negative dust controls which would have permitted an
13 exact assessment of the talc's carcinogenicity
14 relative to the two control dusts?"

15 Do you remember reading that?

16 A. I see it here.

17 Q. They said further:

18 "In light of these shortcomings, a panel of
19 experts at the 1994 IS RTP/FDA workshop declared the
20 1993 NTP study has no relevance to human risk."

21 Did you cite that on direct examination?

22 A. Did I cite this statement or that workshop? I'm
23 not sure what the question is here.

24 Q. Did you cite anything to the Court in your
25 direct examination testimony to the effect that the

1 shortcomings of the NTP rat study would be made
2 available to the Court?

3 A. I'm a little confused. I cited the study where
4 the NTP study showed that adrenal cancers developed in
5 female mice as well as alveolar bronchial which are
6 lung cancers.

7 Q. Do you see this letter you have in front of you,
8 the exhibit which has the FDA letter? Did you see
9 that at the time that you formed your opinions in this
10 case relying upon the NTP rat study?

11 A. I did see this, and I saw this is a letter
12 describing officials' opinion. I didn't see the full
13 report. I don't know what that workshop was. I don't
14 know if they published in a peer review.

15 All I know, I was able to see the NTP rat
16 study, evaluated it, saw that there was cancer
17 developing in animals exposed to talc, and that's why
18 I cited that. But I believe this letter also then
19 does mention that migration is incontrovertible.

20 Q. Next you cited under "in vitro studies" the
21 Fletcher and Saed study from 2018. Right?

22 A. I see that's here, yes.

23 Q. You know Dr. Saed already testified here in
24 court, right?

25 A. Yes.

1 Q. Do you agree -- have you read Dr. Saed's
2 testimony from this proceeding?

3 A. No, I have not.

4 Q. Let me put this in front of you and ask you a
5 question. This is the transcript from the other day
6 from the examination of Dr. Saed. You see there it is
7 on page 119 of the transcript from the other day.

8 A. Is this a final transcript?

9 Q. It is. My question to you is: Do you agree
10 with Dr. Saed that prior to his analysis in 2018 and
11 the work that he has done in connection with his
12 retention by the plaintiffs' counsel in this matter
13 that there was not enough evidence to establish a
14 direct link and precise mechanism developing in
15 association between talc use and ovarian cancer?

16 MS. PARFITT: Objection, your Honor. I do not
17 believe we have a final sworn copy of that transcript.
18 She's been asked about testimony out of context. One
19 section of Dr. Saed's has nothing before or after
20 that, no foundation what Dr. Saed had said.

21 MR. WILLIAMS: I'll ask the question separate
22 and apart from the transcript.

23 THE COURT: I don't know if you reserved the
24 right to review the transcripts. I believe these are
25 final transcripts.

1 (Pause.)

2 THE COURT: So they have to go over them.

3 MS. PARFITT: The other would be, I don't
4 believe Dr. Saed looked at the NTP study. It goes to
5 my response; it is one question taken out of context
6 with all of Dr. Saed's testimony having no idea
7 whether Dr. Saed looked at the NTP study.

8 THE COURT: I think he moved on from the NTP.
9 I think he went on to another study, the Fletcher/Saed
10 study.

11 MR. WILLIAMS: That's correct.

12 BY MR. WILLIAMS:

13 Q. My question to you, separate and apart from what
14 the final transcript will reflect, is Dr. Saed's
15 testimony: As you sit here today, as a scientist, do
16 you believe that as of 2018, there was not enough
17 evidence to establish a biological mechanism, or, in
18 particular, a direct link and precise mechanism for
19 the association between talc use and ovarian cancer,
20 do you think it had already been established prior to
21 2018?

22 A. I'm not a basic scientist. I'm not a biologist.
23 What I look at in these studies for biological
24 plausibility -- I don't know what biological proof is
25 available. I didn't do a systematic total review of

1 the biology. And so I feel like I can't answer that
2 question.

3 Q. So you are telling the Court it is not your
4 area. Is that accurate? Is that a fair statement?

5 MS. PARFITT: Objection, your Honor.

6 MR. WILLIAMS: She was nodding in the
7 affirmative.

8 THE COURT: I'll let the answer go.

9 Q. Let's go to some epidemiology.

10 Dr. McTiernan, for this litigation -- strike
11 that.

12 Q. What I want to ask you now is a set of questions
13 relating to the fit between the conclusions of a
14 causal association between talc use and ovarian cancer
15 as reflected in the studies that you cite in your
16 report and the conclusions of those studies
17 themselves. Do you have that topic in mind?

18 A. I do now, yes.

19 Q. For this litigation, you reviewed what you
20 assessed to be relevant published epidemiological
21 evidence concerning perineal use of talcum powder
22 products and ovarian cancer. Right?

23 A. Yes.

24 Q. You reviewed 38 publications in scientific
25 journals. Right?

1 A. Yes.

2 Q. Based on that review, it is your opinion that
3 evidence of an association between genital use of talc
4 powders and increased risk of ovarian cancer risk is,
5 in your words, highly consistent. True?

6 A. I've looked at the data from those individual
7 studies and at the meta-analyses, and from that I
8 concluded what you just stated.

9 Q. Let's take a look at your report. It is Exhibit
10 C 7 in your book, and for you, Dr. McTiernan, that
11 would be in Volume 2.

12 MR. WILLIAMS: For your Honor it would be in
13 Volume 3. And if we could go to page 64, and the
14 heading "Consistency of Association," page 64. If we
15 can pull that up.

16 Q. Do you see, Doctor, on that page, page 64, that
17 you wrote:

18 "Across the case control and cohort studies,
19 the association between use of talcum powder products
20 and risk of ovarian cancer was highly consistent"?

21 A. Which page are you on?

22 Q. I'm on page 64, Dr. McTiernan.

23 Did I read that right? Was that your
24 conclusion?

25 A. Yes.

1 Q. Let me ask you now to look at one of the studies
2 you reviewed. It is called the Berge study. It is
3 from 2018. It is in your notebook at Exhibit A 11.

4 MR. WILLIAMS: Your Honor, also in your first
5 binder.

6 A. I have it.

7 Q. What we could do, Doctor, if at any time you
8 want to see the study itself, of course, you may. You
9 may also check me by looking at the screen to see if I
10 am reading correctly.

11 Are you on Exhibit A 11, the Berge study?

12 A. Yes.

13 Q. The Berge study is one of the two recent
14 meta-analyses that you consider to be excellent.
15 Right?

16 A. Yes.

17 Q. The excellence of the Berge study, as you
18 describe it, is actually one of the reasons why you
19 say in your report that you did not conduct your own
20 meta-analysis in this litigation. Correct?

21 A. Yes.

22 Q. Please look at the abstract on the cover page of
23 the Berge 2018 paper. It is just below the list of
24 authors. Do you see that right at the beginning?

25 A. The abstract, yes.

1 Q. When you read this study, the very first thing
2 that you said, as follows:

3 "Some fecal studies suggest an association
4 between genital use of talc powder and increased risk
5 of ovarian cancer, but the evidence is not
6 consistent."

7 That's what you read at first. Correct?

8 A. Yes.

9 Q. Let me ask you to focus on the last part of that
10 statement where the authors described that the
11 evidence suggesting an association between genital
12 talc use and ovarian cancer was not consistent.

13 My question is: Did you disagree with that
14 description of the evidence of the authors? Right.

15 A. Yes. I would like to add, most meta-analyses
16 are systematic reviews, would state something along
17 that line in order to justify publishing a
18 meta-analysis. Otherwise, the journal might say, Why
19 publish a meta-analysis? They have to give some
20 justification.

21 Q. Are you now saying the authors of the Berge
22 study did not in fact believe that the evidence of an
23 association between genital talc use and ovarian
24 cancer was not consistent? Are you testifying as to
25 their state of mind?

1 A. I don't know what the state of mind was. I know
2 this is a justification statement, a sort of
3 justification that's pretty standard in a
4 meta-analysis.

5 Q. As far as the Court is concerned, for purposes
6 of assessing your reliance on this study, have we
7 accurately set forth on the board your conclusion that
8 the association was highly consistent and the Berge
9 study conclusion that the evidence was not consistent?

10 A. This is what I stated, and I looked at the data
11 such as in Figure 2 of their paper, which is very
12 consistent to the forest plot here figure in the Berge
13 paper, shows consistency across the studies in terms
14 of the relative risk.

15 Q. When you review a study, it is your practice to
16 always look at both the relative risk that is reported
17 and statistical significance. Right?

18 A. When I look at a study I look at the relative
19 risk and the statistical test the authors used to
20 describe the relative risk.

21 Q. You always look at both the relative risk and
22 the statistical significance. True or not true?

23 A. I always look at the relative risk and the
24 results of whatever test they have done, whatever
25 statistical testing they have done.

1 Q. Whatever statistical testing they have done you
2 look at it?

3 A. Yes.

4 Q. And you consider that along with the reported
5 relative risk. Right?

6 A. Yes.

7 Q. Statistical significance is what epidemiologists
8 use that a likelihood of a relative risk or other
9 estimate of risk did not just occur by chance.
10 Correct?

11 A. That's not a full explanation of the statistical
12 test, and I gave a wider explanation this morning, or
13 the real explanation of what these mean. I think in
14 my report, my expert report, I talked about chance,
15 but what a p-Value really is is the probability that
16 you will make an error if you reject the hypothesis of
17 no association. The confidence interval, the
18 95 percent confidence interval is the likelihood of
19 finding a relative risk in that range if you knew the
20 universe of what a relative risk was. So it is a
21 little more extensive than just something by chance.

22 Q. Statistical significance is what epidemiologists
23 use to determine the likelihood that the relative risk
24 or other estimate of risk did not just occur by
25 chance. Correct?

1 A. I'm not sure what you are reading from.

2 Q. Your report.

3 A. I remember I put that in. What I explained this
4 morning was the statistical reasoning, the statistical
5 explanation of what the p-Value means.

6 Q. Let me ask you look at page 13 of your report,
7 which is Exhibit C 7, the statistical analysis
8 section, the fourth sentence there. You wrote:

9 "To determine the likelihood of these being
10 true estimates of risk, rather than just occurring by
11 chance, epidemiologists determine the statistical
12 significance."

13 That's what you wrote. Right?

14 A. Yes.

15 Q. For the relative risk odds ratio and the hazard
16 ratio estimates, epidemiologists calculate a
17 confidence interval. Right?

18 A. Which shows the range of values the true risk
19 estimate likely represents.

20 Q. And most commonly epidemiologists use a
21 95 percent confidence interval. Right?

22 A. The rest of the sentence, which means we are
23 95 percent sure a true relative risk or odds ratio
24 lies within that interval.

25 Q. You wrote most commonly we -- you were referring

1 to was what was epidemiologists?

2 A. Yes.

3 Q. We epidemiologists use 95 percent confidence
4 interval, which means we are 95 percent sure that a
5 true relative risk or odds ratio lies within that
6 envelope of numbers. Right?

7 A. Yes. It's consistent with what I described this
8 morning.

9 Q. If a confidence interval -- and there is a lot
10 of talk whether it includes one, so I want to make
11 sure this is clear.

12 If a confidence interval includes the number
13 1.0, then you say the association between the exposure
14 and the disease could be null. Correct?

15 A. Yes. That's consistent with the previous
16 sentence that it could lie in that interval and that
17 could be one if it includes that.

18 .

19 Q. "Null" means nonexistent. Right?

20 A. "Null" means a relative risk of one meaning no
21 association. So, yes, it could lie within that
22 interval. If the interval includes one, it could be
23 one.

24 Q. It could be null. Correct?

25 A. It could be a relative risk of one.

1 Q. Relative risk of one means null?

2 A. It means no association.

3 Q. So "null," as you just said, there is no
4 association between the exposure and the disease.
5 True?

6 A. If the relative risk is one, the estimate is
7 there is no association between exposure and the
8 disease.

9 Q. Slightly different from what you wrote. What
10 you write is:

11 "If a confidence includes the number 1.0, not
12 that it was 1.0, or if it includes or passes over 1.0,
13 you say that the association between the exposure and
14 the disease could be null." Right?

15 A. With emphasis on the word "could," that the
16 relative risk could be contained in that interval, if
17 that interval includes one, it could be 1; but it
18 could be any number between 1 and the top of the
19 interval, and any number between 1 and the bottom of
20 the interval. It doesn't tell us it's going to be 1,
21 negative or positive. Somewhere in that interval.
22 Again, it is a 95 percent probability estimate.

23 Q. As you said a moment ago, "null" means no
24 association. Right?

25 A. If the relative risk fell on that, that would be

1 null. That's why I say if 1.0 is in the confidence
2 interval, then it could be a null association, but it
3 doesn't mean it is. It means it could.

4 Q. Where a confidence interval crosses 1.0, as an
5 experienced epidemiologist, you say that the
6 association was not seen. Right?

7 A. Can you cite to where I said this?

8 Q. I'm asking whether you believe that.

9 A. Maybe you can state it again then.

10 Q. Surely.

11 As an experienced epidemiologists, where
12 confidence interval crosses 1.0, the association was
13 not established, was not seen. Correct?

14 A. This is something that I've stated? Are you
15 citing something?

16 Q. I'm asking you a flat out question, which I'm
17 entitled to do. So my question is:

18 As an experienced epidemiologist, where
19 confidence interval crosses 1.0, you say that an
20 association was not seen, not established?

21 A. I think the real explanation of a confidence
22 interval is that if it includes 1.0, it could be a
23 null association. It could fall anywhere within the
24 interval, and I think I'm saying the same thing -- go
25 ahead.

1 Q. Have you completed your answer?

2 A. Yes.

3 Q. Let's go on to the Berge study. We've already
4 talked about it a little bit. It is Exhibit A 11. I
5 would like to go to Figure 2, which is the forest plot
6 set forth in that study on page 8.

7 Figure 2 of the study identifies 27 different
8 epidemiologic studies. I'm focusing on the
9 case-control studies portion of that chart. Right,
10 Doctor?

11 A. Yes.

12 Q. It identifies 27 epidemiologic studies, 24 which
13 are retrospective case-control studies and three
14 prospective cohort studies. Right?

15 A. Yes.

16 Q. Figure 2 shows the overall association between
17 "ever" use of genital talc and the risk of ovarian
18 cancer in the 27 studies. Correct?

19 A. Yes.

20 Q. The associations that are reported in this
21 Figure 2 are estimated as relative risks, right, in
22 the column over to the right?

23 A. Yes.

24 Q. And they are set forth with a 95 percent
25 confidence interval. Right?

1 A. Yes.

2 Q. Let me ask you about one of the studies here so
3 that we can understand how you applied concepts like
4 statistical significance and confidence intervals in
5 reaching your opinion.

6 Take a look at the reference to the Goodman
7 study. That case-control study, like all of the other
8 case-control studies, listed here was retrospective in
9 design. Right?

10 A. Yes.

11 Q. Retrospective studies are backwards, looking
12 where people are asked questions after they have
13 contracted the disease, and they are asked to recall
14 what they put on or in their bodies. Correct?

15 A. I would clarify, because the cases are the ones
16 that have developed the disease, if it is a
17 population-based study. The cases develop the disease
18 and they asked about exposures; retrospectively, the
19 controls have not have a disease, so they are asked
20 about their exposure typically at a time when the
21 cases had developed their disease. They usually are
22 asked to remember back some time. I think your
23 distinction sounded like everybody had a disease.
24 That's what I was trying to clarify.

25 Q. The cases have disease; the controls do not.

1 Correct?

2 A. Correct.

3 Q. Both groups of people are asked the same
4 questions; are they not?

5 A. Yes.

6 Q. Let's go back to the Goodman 2008 study. The
7 relative risk for the Goodman 2008 study is 0.99. Do
8 you see that?

9 A. Yes.

10 Q. The relative risk has a 95 percent confidence
11 interval. Correct?

12 A. Yes.

13 Q. Now, to be clear, that confidence interval does
14 not mean that the true relative risk is in fact 0.99
15 as opposed to, say, 0.80 or 1.0 or 1.2. Correct?

16 A. That's correct. The confidence interval does
17 not tell you the relative risk. It just gives you a
18 likely range.

19 Q. Instead, that confidence interval means that we
20 can be sure, 95 percent sure that a true relative risk
21 lies somewhere within the two numbers in the
22 parenthesis. Correct?

23 A. I think the statisticians wouldn't talk so much
24 about surety, but the rest of your statement is
25 correct. It is an estimate that if you knew the

1 totality of the universe of evidence, that with
2 95 percent confidence it would fall within those
3 intervals. It is still saying a very similar thing.
4 It is just that word "surety" is not guaranteed from
5 statistical tests.

6 Q. Looking at the high end of the confidence
7 interval, the 1.4 number that would indicate genital
8 talc use is potentially associated in the Goodman
9 study with a 41 percent increased risk of developing
10 ovarian cancer. Correct?

11 A. I think it is not talking about the individual
12 study, the confidence interval. It is talking about
13 the probability in a universe of what the relative
14 risk could lie in. That's what I'm saying. In the
15 Goodman study we know what the relative risk shows.
16 In this case, it shows .99. So the confidence
17 interval doesn't move the relative risk within a
18 study. It talks about what the universe of
19 information might be.

20 Q. Dr. McTiernan, did something in my question
21 suggest to you I was saying the actual number was
22 0.99?

23 A. Maybe I misheard you. I thought you said in the
24 Goodman study it would be such.

25 Q. We established a moment ago the 0.99 does not

1 mean that it is necessarily the correct number.

2 Right?

3 A. In the universe. I don't remember saying that.

4 Maybe I responded to something I didn't mean to. We

5 know what the relative risk is in the Goodman study.

6 We don't know what the true relative risk is in the

7 universe of people with and without ovarian cancer.

8 Q. All I'm trying to establish is that the numbers

9 that are within the parenthesis set forth a range, and

10 it suggests in the Goodman study at least that the

11 relative risk could reflect a 41 percent increase in

12 the chances of getting ovarian cancer; but at the low

13 end it could reflect a 30 percent decreased risk of

14 getting ovarian cancer. Right?

15 A. I think as long as you are not suggesting that

16 the Goodman study relative risk is different from what

17 it is. It is talking about if you did the study

18 again, another study, the universe of information, the

19 relative risk could fall within that category given

20 the results in that one study.

21 Q. Can I get a yes or no?

22 THE COURT: He's basing it on the Goodman

23 study. He's not talking about what might happen

24 again. He's trying to get an answer what those

25 numbers reflect in this particular study for this

1 study. Isn't that right?

2 MR. WILLIAMS: That's correct.

3 THE COURT: You can answer that. Right?

4 THE WITNESS: It is difficult. My
5 understanding of statistics is relative risk doesn't
6 change based on what the confidence interval is. The
7 relative risk is what it is. The confidence interval
8 just tells us how we can infer this outside study,
9 what the true relative risk might be. That's my
10 understanding.

11 BY MR. WILLIAMS:

12 Q. Is that an understanding you've come to since
13 the time you have prepared your report?

14 A. I've done more full reading, yes. The American
15 Statistical Association has come out with some new
16 position statements, new statements about --

17 MR. WILLIAMS: Can I cut her off, your Honor?

18 THE COURT: You don't have to tell us what it
19 is. All he asked is, and he said yes.

20 Q. You have a different opinion now than at the
21 time you wrote your report. Yes or no?

22 A. It is more fully informed.

23 Q. Because the confidence interval in Goodman 2008
24 includes the number 1, that means that the association
25 reported in that study could be null. Correct?

1 A. I would say the true relative risk could be
2 null.

3 Q. You cannot rule out the possibility that there
4 is no association between ever genital talc use and
5 ovarian cancer in the Goodman study because of the
6 results that were reflected here which passed through
7 1.0. Right?

8 A. You are saying you cannot rule out no
9 association between genital talc use and risk of
10 ovarian cancer?

11 Q. Precisely.

12 A. To that I would say yes.

13 Q. Let's take a look at the entire Figure 2 on this
14 page. It consists of 24-case-control studies, and
15 then there are the three cohort studies down below.
16 Right?

17 A. Yes.

18 Q. Looking at the top of the forest plot Figure 2,
19 do you see the Hartge 1983-case-control study, second
20 one down from the top. Do you see that?

21 A. Yes.

22 Q. That study as well includes the number 1.0
23 meaning the low end of the interval is below 1.0.
24 Right?

25 A. Yes.

1 Q. If we can go through this quickly. The same is
2 true for Whittemore, 1983, right, the confidence
3 interval falls below 1.0?

4 A. Yes.

5 Q. Both 1999?

6 A. Yes.

7 Q. Harlow and Weiss, 1989?

8 A. Yes.

9 Q. Chen, 1992?

10 A. Yes.

11 Q. Rosenblatt, 1992?

12 A. Yes.

13 Q. Tzonou, 1993?

14 A. Yes.

15 Q. Godard, 1998?

16 A. Yes.

17 Q. Wong, 1999?

18 A. Yes.

19 Q. Goodman, 2008, that's what we just discussed.

20 Right?

21 A. Yes.

22 Q. Merritt, 2008?

23 A. Yes.

24 Q. And Rosenblatt 2011?

25 A. Yes.

1 Q. So if we just looked at those case-control
2 studies that had a confidence interval that crosses
3 over 1, there are 12 of them, 12 of the 24. Correct?

4 A. Yes.

5 Q. Half of the case-control studies in the Berge
6 2018 meta-analysis have confidence intervals that
7 include the number 1.0. Right?

8 A. Yes.

9 Q. That means that there are case-control studies,
10 the results of which are not statistically
11 significant. Correct?

12 A. If we look at the sample size, which I talked
13 about this morning, the smaller studies tend to have
14 very small -- tend to have wide confidence intervals.
15 So, yes, all of these confidence intervals include 1.

16 Q. And that means there are 12 that are not
17 statistically significant. Correct?

18 A. If you are using the term "statistically
19 significant" to indicate that the confidence interval
20 includes 1, the answer is yes.

21 Q. Let me ask you to look at your red binder at
22 your deposition testimony, and I'll direct you to page
23 245. I'm directing your attention to page 245 through
24 line 24, to page 246, line 1.

25 "QUESTION: And that means that there are 12

1 that are not statistically significant. Correct?

2 "ANSWER: Yes.

3 Was that your answer then?

4 A. Yes.

5 Q. The overall association in half of the studies
6 in Berge could be null. Correct?

7 A. Yes.

8 Q. There in fact is no association between genital
9 talcum powder use and ovarian cancer in those
10 case-control studies. Right?

11 A. No, I wouldn't say that.

12 Q. If the confidence interval includes the number
13 1.0, then we can say that the association between the
14 exposure and the disease could be null. Correct?

15 A. It could be null. I think your next statement
16 was that there was no association. So that's not the
17 same as could be no association. I think you asked me
18 that there was no association. So there is a
19 difference between was no association and could be no
20 association.

21 Q. We went to the case-control retrospective
22 studies, but we haven't discussed the prospective
23 studies, so let's do that now.

24 You did a Bradford Hill analysis here, and you
25 put up those factors on the board. Right?

1 A. Yes.

2 Q. Let's take out what we have marked as Exhibit A
3 63, which is a Bradford Hill presentation. If you
4 turn to page 1 of Exhibit A 63, do you recognize as
5 the address by Sir Bradford Austin Hill that
6 identifies what has become known in your field as the
7 Bradford Hill factors or criteria?

8 A. Yes.

9 Q. Please turn to page 2 of Exhibit A 63, the
10 right-hand column, first full paragraph. That is Sir
11 Bradford Hill's description of consistency. Right?

12 A. Yes.

13 Q. He writes:

14 "Next on my list of features to be specially
15 considered I would place the consistency of the
16 observed association. Has it be repeatedly observed
17 by different persons in different places,
18 circumstances, and times?"

19 Right?

20 A. Yes.

21 Q. Now, please turn to page 4 and look at the left
22 column, the very top paragraph that carries over from
23 the previous page. There is a sentence there that
24 begins with:

25 "I myself would put a good deal of weight

1 upon:

2 A. Can you please tell me where you are. My page 4
3 of the Bradford Hill first paragraph starts "A
4 particular occupation" --

5 Q. Can you see the page in the upper right-hand
6 corner, it should have 297 on it?

7 A. Okay.

8 Q. Left-hand column, first sentence:

9 "I would myself put a good deal of weight upon
10 similar results reached in quite different ways, for
11 example, prospectively and retrospectively."

12 Right?

13 A. Yes.

14 Q. He is saying, I think there should be particular
15 weight if there's consistency with retrospective
16 studies or forward looking studies.

17 Right?

18 A. I don't see the word "should." I see he said he
19 would put a good deal of weight on similar results
20 reached in quite different ways, for example,
21 prospectively and retrospectively.

22 Q. In your opinion, the association between the use
23 of talcum powder products and the risk of ovarian
24 cancer is consistent across study designs,
25 specifically across case-control studies and cohort

1 studies?

2 A. As I looked at the data this morning on the
3 forest plot, I saw consistency that most of the
4 studies were to the right of the line, most were in
5 the positive direction, the relative risk.

6 Q. We put up your report earlier under the second
7 heading "consistency." Do I need to put that up
8 again? It said:

9 "Across the case-control and cohort studies,
10 the association between the use of talcum powder
11 products and risk of ovarian cancer was highly
12 consistent."

13 Do you remember? Do you recall that?

14 A. Yes.

15 Q. The idea of a prospective cohort study, is that
16 people are asked what they do and what they put on,
17 and in their bodies right now when they are healthy,
18 and then they are followed along? Correct?

19 A. Yes.

20 Q. You reviewed the Gertig 2000 study reporting on
21 the Nurses' Health Study cohort. Right?

22 A. Yes.

23 Q. You reviewed the Gates 2008 paper also relating
24 to the Nurses' Health Study. Right?

25 A. Part of the 2008 was Nurses', part was a

1 case-control study.

2 Q. You reviewed it?

3 A. Yes.

4 Q. You reviewed Gates 2010 also relating to the
5 Nurses' Health Study. Right?

6 A. Yes.

7 Q. You reviewed the Houghton 2014 study?

8 A. Yes.

9 Q. That report relates to the Women's Health
10 Initiative on which you worked. Right?

11 A. Yes.

12 Q. You also reviewed the Gonzalez 2016 study
13 reporting on the Sister Study cohort. Right?

14 A. Yes.

15 Q. Those are five papers reporting results from
16 three prospective cohort studies that you reviewed.
17 Right?

18 A. Yes.

19 Q. True or not true: Every single one of the
20 prospective cohort studies that you reviewed in
21 forming your opinions in this case reports an overall
22 risk estimate for genital talc use and ovarian cancer
23 that has a confidence interval crossing 1.0?

24 A. Yes. Usually I talk about the relative risk and
25 then I talk about the confidence interval. I don't

1 usually talk about just one, but, yes.

2 Q. I'm not asking you what you talk about. Is the
3 answer to my question yes?

4 A. As an epidemiologist, I don't just talk about
5 confidence intervals and about p-Values. I talk about
6 relative risk for consistency.

7 THE COURT: When he asks you a question,
8 respond to the question that he has.

9 THE WITNESS: Okay.

10 THE COURT: He is only focusing on that for
11 the moment. I know we've heard your testimony about
12 how you viewed it all day tomorrow, so we understand
13 that.

14 MR. WILLIAMS: Thank you, your Honor.

15 Q. In 100 percent of the prospective cohort studies
16 there was no overall association found between genital
17 talc use and ovarian cancer. Correct?

18 A. I would have to disagree with that.

19 Q. If confidence interval includes the number 1,
20 then we say the association between the exposure and
21 the disease could be null. Correct?

22 A. I agree with that.

23 Q. In 100 percent of the prospective cohort studies
24 you could not rule out the possibility that the true
25 relative risk in each and every one of the prospective

1 studies is null. Correct?

2 A. I cannot -- say it again. Just repeat it. I
3 think it's close to what I understand, but, please.

4 Q. You cannot rule out the possibility that the
5 true relative risk in each and every one of the
6 prospective cohort studies is null?

7 A. Correct.

8 Q. "Null" means zero, right, nonexistent?

9 A. It means non-association or a relative risk of
10 1.

11 Q. You cannot identify any prospective cohort study
12 concluding that there was a statistically significant
13 overall association between talc use and ovarian
14 cancer. True?

15 A. True.

16 Q. It is your opinion an association between
17 genital talc use and ovarian cancer risk is highly
18 consistent across case-control and cohort studies
19 across those study designs. That's your opinion.
20 Right?

21 A. Yes.

22 Q. One of the reasons that you did not perform your
23 own meta-analysis in this case was because you
24 believed the recently published Penninkilampi and
25 Berge meta-analyses were in your words excellent

1 studies. Right?

2 A. Yes.

3 Q. Both of those studies included a meta-analysis
4 that stratified or broke-out study design, right?
5 They described cohorts and described case-controls
6 separately. Correct?

7 A. Yes.

8 Q. Both Penninkilampi and Berge included an odds
9 ratio for the combined retrospective and case-control
10 studies on the one hand and a separate odds ratio for
11 the combined prospective cohort studies. Right?

12 A. I want to look at both of them. Berge, I
13 believe so; and Penninkilampi, I would like to look at
14 again.

15 Q. This is A 109, and I'm referring to page 6,
16 Table II. That is a summary of pooled effect sizes in
17 a subgroup analysis. Right, Doctor?

18 A. Yes.

19 Q. And it shows an overall association between any
20 perineal talc use and ovarian cancer stratified by
21 study design estimated as an odds ratio. Right?

22 A. Yes.

23 Q. And looking at the stratified analysis in Table
24 No. 2, the combined odds ratio for the case-control
25 study was 1.35 with a 95 percent confidence interval

1 of 1.27 to 1.43. Do you see that?

2 A. Yes.

3 Q. The study also shows the combined odds ratio for
4 the cohort studies. Right?

5 A. Yes.

6 Q. The three cohort studies are listed there.
7 Correct?

8 A. Yes.

9 Q. And in that analysis that you rely upon for your
10 opinions, at the combined odds ratio for the cohort
11 studies was 1.06 with a 95 percent confidence interval
12 of 0.90. Right?

13 A. Confidence interval, that was the lower?

14 Q. Yes. It is right on the board there. Do you
15 see any perineal use?

16 A. I didn't hear the upper limit.

17 Q. The upper limit is 1.25. Do you see that?

18 A. Yes.

19 Q. This includes the null, which is the possibility
20 that there is in fact no association at all between
21 genital talc use and ovarian cancer. Right?

22 A. Yes.

23 Q. Let's go to the Berge study. That's Exhibit A
24 11. Do you have that in front of you?

25 A. Yes.

1 Q. I direct your attention to Figure 2 on page 8.
2 If we pull out that chart, if we could look at the
3 bottom, a subtotal, and do you see the subtotal --
4 that's the wrong one -- the subtotal for the cohort
5 studies is 1.02. We can agree that is an
6 extraordinarily low point estimate?

7 A. It's low, yes.

8 Q. And the confidence interval is 0.87 on the low
9 end and the upper end is 1.20. Right?

10 A. 0.85.

11 Q. 0.85. And the upper limit is 1.20. Did I read
12 that right?

13 A. Yes.

14 Q. So the same confidence interval indicates that a
15 true combined risk estimate for the cohorts within
16 that range is as high as a 20 percent increased risk
17 and as low as a 15 percent decreased risk. Right?

18 A. Again, you are talking about -- the way I read
19 this is that the relative risk, the meta-analysis for
20 those three cohorts is a 1.02 relative risk with a
21 confidence interval that we just mentioned. So that
22 indicates a confidence interval -- indicates what the
23 relative risk may truly be in the universe of cohort
24 studies. That's what I'm trying to say. I'm not sure
25 that confidence interval means that those three cohort

1 studies, their relative risk would be in that
2 interval, and you could already see the relative risk
3 for one of them falls outside of it.

4 That's why I'm saying when I look at a
5 confidence interval it means this is what a true
6 relative risk could fall within.

7 Q. You would agree that the confidence interval at
8 the upper end would indicate a 20 percent increased
9 risk. Right?

10 A. Yes.

11 Q. And equally true, based on the confidence
12 interval reported on page 7 of this exhibit, that the
13 relative risk could be as low as 0.85. Correct?

14 A. Yes.

15 Q. Let me ask you some questions about power
16 calculation. We have been talking about the cohort
17 studies, and I understand you have some criticisms of
18 the cohort studies. Is that fair?

19 A. There are strengths and limitations of both
20 cohort and case-control studies.

21 Q. One reason that you have stated for the lack of
22 statistical significance in the cohort studies is that
23 the number of cases, the sample size of cancer cases
24 in those studies is too low. Right?

25 A. Yes.

1 Q. You are distinguishing between the total sample
2 size on the one hand meaning every woman in the study
3 versus those women in the study who have cancer.

4 Right?

5 A. The power to determine the relative risk depends
6 on the number of cases.

7 Q. What is important for your analysis in terms of
8 the sample size is the number of cancer cases.

9 Correct?

10 A. Yes.

11 Q. You believe that the number of cancer cases
12 affects the statistical power of these cohort studies
13 we have been discussing. Right?

14 A. Individually, yes.

15 MR. WILLIAMS: This is Dr. McTiernan's
16 testimony at page 215, lines 16, through the same
17 page, line 18:

18 Q. (Reading.)

19 "QUESTION: Do you believe that the number of
20 cases affects the statistical power of the studies"?

21 Q. Line 16.

22 (Reading.)

23 "ANSWER: Yes.

24 "QUESTION: You believe the number of cases
25 affects the statistical power of the studies?

1 "ANSWER: Yes."

2 Now, you performed your own power calculation
3 to determine the sample size that you believe is
4 required for a study to have sufficient power to
5 detect a statistically significant association.
6 Right?

7 A. Yes.

8 Q. And one of the reasons why you believe that the
9 meta-analyses that have been done in the last, say,
10 five years are helpful is that they are able to
11 combine the number of cancer cases. True?

12 A. Because they have additional power because they
13 have many more cases.

14 Q. And the way that you get many more cases is by
15 combining the number of cancer cases among the
16 studies. Correct?

17 A. My understanding is meta-analyses' power
18 calculations don't just add together numbers. I
19 haven't done the power calculations myself, but it is
20 not the same as adding. But, conceptually, more cases
21 provides more power. I just can't say that you would
22 apply the same power calculation to a meta-analysis
23 and then immediately get the right answer.

24 Q. Let's get the record clear.

25 You have testified that you personally have

1 performed what is known as a power calculation to
2 determine the sample size that you believe is required
3 for a study. Correct?

4 A. An individual study, yes.

5 Q. And you place particular importance on that
6 because you are focused on the number of cancer cases.
7 Right?

8 A. Yes, in individual studies particularly.

9 Q. Your calculation, the one in your litigation
10 report, you defined "good power" as power sufficient
11 to detect a relative risk of 1.3 with the statistical
12 significance of 0.05. Right?

13 A. Yes.

14 Q. Based on your calculation, you concluded that
15 you have good power the number of cases would need to
16 be 931. Correct?

17 A. Yes.

18 Q. None of the cohort or case-control studies that
19 you reviewed had sample sizes that large. Right?

20 A. Correct -- sorry. None of the case-control or
21 cohort?

22 Q. Correct.

23 A. I think some of the case-control studies do have
24 sample sizes that big.

25 Q. Almost none of the case-control and cohort

1 studies?

2 A. I would need to look at the numbers. There are
3 several that have more than 931, but it is not the
4 majority.

5 Q. For that reason it was your opinion the
6 evaluation of the meta-analysis and the pooled
7 analyses with their larger sample sizes is critical to
8 understanding the state of the evidence. Right?

9 A. Yes.

10 Q. And you wrote in your report on page 48, Exhibit
11 C 7, page 48, the meta-analysis section, bottom half,
12 after that hyperlink:

13 "Lack of statistical significance found in the
14 various studies is likely due to their small sample
15 sizes. For this reason, evaluation of the
16 meta-analysis and pooled analysis with their larger
17 sample sizes is critical to understanding the state of
18 epidemiological evidence linking use of talcum powder
19 products to risk of ovarian cancer."

20 Correct?

21 A. Yes.

22 Q. These meta-analyses, they look at the number of
23 cases across the cases that are part of the
24 meta-analysis. Right?

25 A. Say it again.

1 Q. The meta-analyses look at -- the meta-analyses
2 and the pooled analyses, with their larger sample
3 sizes, derive their larger sample sizes by taking the
4 sample sizes from multiple other studies and putting
5 them together. Right?

6 A. Yes. In terms of power, however, it is not as
7 simple as adding them up together. You get more power
8 by doing the meta-analysis, but it is a different
9 power calculation to my knowledge. Doing a
10 meta-analysis corrects for much of the lack of numbers
11 in individual studies, but it doesn't completely
12 correct it from my understanding because of the
13 variability in the individual studies. That's why I
14 don't want to say you immediately have completely
15 enough power by adding studies together. I know there
16 are power calculations that are done specifically for
17 meta-analyses.

18 Q. The point that you were making in performing
19 your power calculation -- let me stop for a second.
20 You performed a power calculation, did you not?

21 A. I did to consider for individual studies.

22 Q. The point you were making in performing your
23 power calculation was that with meta-analysis, with
24 their larger combined sample sizes, that could be used
25 to overcome the lack of statistical power. True?

1 A. The word "could" is key here, yes.

2 Q. Did you understand me to be saying "could"?

3 A. I thought I heard the word "could," that it
4 could overcome the lack of power in individual studies
5 -- maybe you could repeat what you said.

6 Q. I'll ask the question again:

7 The point that you were making in performing
8 your power calculation was that meta-analyses with
9 their larger combined sample sizes can be used to
10 overcome that lack of statistical power. Is that
11 true?

12 A. It can correct for much of the problems. It
13 just can't completely correct for individual studies'
14 lack of power, to my understanding.

15 MR. WILLIAMS: Permission to read, your
16 Honor --

17 THE COURT: Yes.

18 MR. WILLIAMS: -- from the Doctor's deposition
19 at page 217, lines 12 through 16.

20 (Reading.)

21 "QUESTION: The point you were making in
22 performing your power calculation was that
23 meta-analyses, with their larger combined sample
24 sizes, can be used to overcome that lack of
25 statistical power. Is that true?

1 "ANSWER: Yes."

2 Q. Now, Doctor, I would like you to take a look at
3 the Berge 2018 meta-analysis, which is Exhibit A 11
4 and I would ask you to turn to page 7.

5 Take a look at the paragraph starting at the
6 top of the right-hand column there, halfway down that
7 paragraph starting with, "It should be noted." Are
8 you with me?

9 A. Yes.

10 Q. The Berge study wrote:

11 "It should be noted that the cohort studies
12 included in the meta-analysis comprised a total of
13 429 cases of ovarian cancer cases exposed to genital
14 talc and 943 unexposed cases. The statistical power
15 of the meta-analysis of these cohort studies to detect
16 an RR of 1.25 similar to the result of the
17 meta-analysis of case-control studies was 0.99. Thus,
18 low power of case-control studies cannot be invoked as
19 explanation of the heterogeneity of the results."

20 Is that what they said?

21 A. Yes.

22 Q. The Berge study is one of the two meta-analyses
23 that you said is an excellent study. Right?

24 A. I'm just noting the 429 cases does not look
25 correct for the cohort studies.

1 Q. I'm asking you a question, Doctor.

2 The Berge study is one of the two
3 meta-analyses that you said is an excellent study.
4 Correct?

5 A. Yes.

6 Q. And what they list here on page 7 of the Berge
7 study is 429 cases or exposed cases of ovarian cancer
8 and 943 unexposed ovarian cancer cases. Right?

9 A. Yes. I misread it. That's what they say.

10 Q. If you add those two numbers together, you get
11 over 3900 actual cancer cases. Right?

12 A. Yes.

13 Q. Now, in your report, based on your power
14 calculation, you concluded that the minimum number of
15 cases would need to be 931. Correct?

16 A. Yes.

17 Q. Can we agree 1372 is more than 931?

18 A. Yes. But my power calculation was for an
19 individual study. However, they have done a power
20 calculation, and I assume they have done it for
21 meta-analysis. So I would trust their statement that
22 the power was .99 rather than extrapolating from my
23 power calculation which was for one study.

24 Q. This Berge study that you say is an excellent
25 study sets forth a power calculation that suggests

1 that lack of power should not be a valid criticism of
2 the cohort studies. Correct?

3 A. Given their power calculation.

4 Q. And you have no reason, as you said a moment
5 ago, to doubt that calculation. Correct?

6 A. Correct.

7 Q. Let me ask some questions about epidemiology and
8 some basic principles.

9 You mentioned on direct examination that you
10 have worked on comprehensive written reports for the
11 U.S. Government in your career?

12 A. Yes.

13 Q. And in the section of your report entitled
14 "Overall Approach," -- if we can pull that up, it is
15 page 7 -- you had an overall section in your report,
16 and you drew upon your years of experience, and you
17 wrote that for purposes of your work here you drew
18 upon that experience with synthesizing and
19 interpreting large numbers of epidemiologic studies
20 for comprehensive reports. Right?

21 Let me draw your attention to this particular
22 part.

23 A. It says, page 9 --

24 THE COURT: He has it up on the screen.

25 THE WITNESS: I see it.

1 Q. (Reading.)

2 "Among the different engagements that you had
3 is work with the World Health Organization
4 International Agency for research on cancer, IARC, and
5 the World Cancer Research Fund" -- correct?

6 A. Yes.

7 Q. (Continuing.)

8 -- "for the World Cancer Research Fund, you
9 are a member of the advisory panel of experts that
10 guides interpretation of meta-analyses and does
11 systematic reviews of nutrition, physical activity,
12 obesity and risk factors for many cancers, including
13 ovarian cancer."

14 Is that true?

15 A. My work on that panel is completed. I'm on an
16 interim panel now.

17 Q. As of the time I took your deposition, you were
18 still on that panel. Correct?

19 A. I might have stated it had recently come to an
20 end. I believe I stated that in the deposition.

21 Q. In your binder, take a look at Exhibit A 153.

22 MR. WILLIAMS: This is the World Cancer
23 Research Fund, Judge, the evidence report.

24 Q. Do you have that in front of you?

25 A. 153 in Binder 1, I don't see it.

1 (Pause.)

2 Q. Do you have that in front of you?

3 A. Yes.

4 Q. Now, the continuous research project that you
5 did for 2018, the purpose of it was to consider
6 scientific research from around the world, and to
7 evaluate that literature and make findings based on
8 it. Is that accurate?

9 A. Yes.

10 Q. The third paragraph explains on the page that we
11 have on the board, which is, I think, page 5 of the
12 document, explains why the CUP does all of its work
13 and it says:

14 "Through this process the CUP ensures that
15 everyone including policymakers, health professionals,
16 and members of the public has access to the most
17 up-to-date information on how to reduce the risk of
18 developing cancer."

19 (Pause.)

20 Do you have that in front of you, Doctor?

21 A. Yes, I do.

22 Q. There is a portion of this report where you and
23 your colleagues explained how to cite the document.
24 It is on page 5. It is another section on the same
25 page, how to cite the third expert report. Correct?

1 A. Yes.

2 Q. So the idea is, this is an actual report that
3 could be cited, and you explain how it could be cited
4 if one chose to do so. Correct?

5 A. Yes.

6 Q. And as of last year, in 2018, you were a member
7 of what was called the "Advisory Panel of Experts For
8 the World Cancer Research Fund." Right?

9 A. Yes.

10 Q. This exhibit, A 153, was published by that
11 organization at the time you served as a panelist for
12 the organization in 2018. Correct?

13 A. This exhibit was published at that time. Is
14 that what you are saying?

15 Q. I'm saying this exhibit was publish by the WCRF
16 at the time you served as a panelist for that
17 organization in 2018?

18 A. Yes.

19 Q. 2018 was two years after you were retained by
20 plaintiffs' counsel. Correct?

21 A. Yes.

22 Q. Let's turn to page 31.

23 You were acknowledged here in the left-hand
24 column at the bottom, and you appear in the photograph
25 that appears on that page. Right?

1 A. Yes.

2 Q. The expert advisory panel that you were on,
3 guided interpretation of meta-analyses and systematic
4 reviews on those topics we discussed, nutrition,
5 physical activity, obesity, and risk for many
6 cancers -- right?

7 A. For those variables specifically, yes.

8 Q. Including ovarian cancer. Correct?

9 A. Yes.

10 Q. Please turn to page 8 of the exhibit. The last
11 paragraph is on study design. That paragraph on study
12 design starts by saying:

13 "Each study design has its advantages and
14 limitations" -- you said that here today?

15 A. Yes.

16 Q. You agree with the WCRF there are good things
17 and bad things about any study. Correct?

18 A. There are good things and bad things --

19 Q. Any study type?

20 A. Yes.

21 Q. True or not true:

22 "The hierarchy of epidemiological evidence
23 places cohort studies above case-control studies?"

24 A. I would note that the top of this section --
25 this is a box issues concerning interpretation of

1 epidemiologic tests.

2 It states:

3 "Interpretation of epidemiologic evidence on
4 identity, nutrition, and physical activity, and the
5 risk of cancer is complex, and expert judgment is
6 essential. General considerations that need to be
7 taken into account when evidence is assembled and
8 assessed include the following" -- and then there are
9 six bullet points, and I believe Mr. Williams is
10 talking about the bottom bullet point under that
11 heading."

12 Q. True or not true:

13 "You and your colleagues published a report
14 that says: The hierarchy of epidemiological evidence
15 places cohort studies above case-control studies with
16 ecological studies and case reports at the bottom.
17 There are merits in considering a number of different
18 study designs. Cohort studies are likely to be the
19 main source of evidence owing to the long latent
20 period for cancer to develop and also to their
21 prospective design. However, in some circumstances
22 case-control studies and ecological studies may also
23 make a useful contribution to the evidence. See
24 Section 7."

25 Did I read that correctly?

1 A. Yes. And that's referring to the diet, physical
2 activity and nutrition variables it mentions at the
3 top.

4 Q. Did I read it correctly?

5 A. Yes.

6 Q. If you look at the last paragraph in the
7 left-hand column -- and I would like to turn to page
8 22 now -- the last paragraph in the left-hand column
9 says:

10 "The work from the 2007 second expert report
11 was used as a starting point." Correct?

12 A. Yes.

13 Q. The acronym SLR in the continuous update project
14 refers to systematic literature review. Correct?

15 A. Yes.

16 Q. Continuing on page 22 of the update project
17 report, it says:

18 "The first stage of the SLRs was a
19 comprehensive search using standardized search
20 strategy -- a standardized search strategy for the
21 scientific literature for randomized controlled trials
22 and cohort studies published since 2006 using
23 MedLine."

24 Right?

25 A. Yes.

1 Q. And it goes on to explain:

2 "Because case-control studies are particularly
3 prone to recall and other bias, they were not
4 routinely reviewed. However, if there were no or very
5 few RCTs or cohort studies, they were included. That
6 was the methodology you employed."

7 Right?

8 A. This is what they stated at the last meeting I
9 was in. They stated that they do include case-control
10 in the search. So here it's clear what they say about
11 review. But the search part is not completely
12 correct.

13 MR. WILLIAMS: Move to strike as
14 nonresponsive.

15 THE COURT: His question was, Is that what the
16 report says?

17 THE WITNESS: Then yes.

18 BY MR. WILLIAMS:

19 Q. For the analysis that you did in this
20 litigation, you reviewed prospective cohort studies.
21 Right?

22 A. You are talking about the current -- the current
23 litigation?

24 Q. Yes. I'm jumping forward to today.

25 A. Yes.

1 Q. The work you have done in this matter you
2 reviewed prospective cohort studies. Right?

3 A. Yes.

4 Q. None of those studies concluded that there was a
5 statistically significant overall association between
6 talc use and ovarian cancer. Right?

7 A. Their conclusion, correct.

8 Q. Would you agree with me that if you had only
9 looked at the cohort studies in this case, like you
10 did as part of the expert advisory panel for the World
11 Cancer Research Fund, you would not have been able to
12 opine talcum powder causes ovarian cancer?

13 A. If I didn't look at the totality of evidence, I
14 might have come up with a different answer.

15 Q. My question was a little different. My question
16 was: If you had only looked at the cohort studies,
17 all of which found no statistically significant
18 association, you would not have been able to come to a
19 conclusion that talc actually causes ovarian cancer.
20 Correct?

21 A. I think I can't assume what I would come up
22 with. I know one of the cohort studies did have a
23 positive association for serous cancer. I haven't
24 considered -- to answer your question, I haven't
25 considered what my conclusion would have been if I

1 looked only at a subset of studies.

2 Q. In your last answer, you mentioned one of the
3 studies found a positive association for serous
4 invasive ovarian cancer. You just said that, right?

5 A. Yes.

6 Q. You are referring to Gertig 2000. Right?

7 A. Yes.

8 Q. You are aware later Gertig studies -- strike
9 that.

10 Later studies that followed the same women
11 along farther in time through 2006, 2008, 2010 did not
12 find a statistically significant positive association
13 between use of talc and serous invasive ovarian
14 cancer. Correct?

15 A. They used a different comparison. It is
16 difficult to say what they would have found if they
17 used the same comparison. So they did not. They
18 compared "ever" users plus "once-a-week" users to
19 "greater" users. I don't know what the relative risk
20 would have looked like had they done the same
21 comparison as the first paper.

22 Q. Let's unpack that. You do not know what the
23 relative risk would have looked like had they used the
24 same criteria, is what you are saying. Right?

25 A. Yes.

1 Q. But you also do not know it would have been
2 different than the finding that they made in 2010.
3 Correct?

4 A. Correct.

5 Q. You do not deny that in 2010, when the women had
6 been followed for a longer period of time, the
7 positive association for serous invasive ovarian
8 cancer fell away and there was no statistically
9 significant association. True?

10 A. There was no association in their data as they
11 presented it.

12 MR. WILLIAMS: Your Honor, is this a good time
13 for a break?

14 THE COURT: Absolutely. Thank you.

15 THE DEPUTY CLERK: All rise.

16 (Recess is taken.)

17 (Continued on the next page.)

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1 THE DEPUTY CLERK: All rise.

2 THE COURT: Thank you.

3

4 **Anne McTiernan**, resumed.

5

6 CROSS-EXAMINATION

7 BY MR. WILLIAMS:

8 Q. Good afternoon, Dr. McTiernan.

9 In your opinion, if risk for disease increases
10 with the amount of exposure, the likelihood of a
11 causal relationship goes up. Right?

12 A. Yes.

13 Q. That is essentially the concept of
14 dose-response. Right?

15 A. Yes.

16 Q. You reviewed the Terry 2013 study, and we
17 referred to that earlier today, which is Exhibit A 31.
18 Do you have that in front of you?

19 A. Yes.

20 Q. In your opinion, the Terry 2013 pooled analysis
21 provides strong evidence that perineal use of talcum
22 powder causes ovarian cancer. Right?

23 A. I'm sorry. You said 831 for the reference, yes.

24 Q. I said A 139. We have it up on the board.

25 It is your opinion that that study provides

1 strong evidence that perineal talcum powder causes
2 ovarian cancer. Right?

3 A. Yes.

4 Q. In your report Exhibit C 7, page 55 of the
5 report, you wrote:

6 "The Terry, et al, pooled analysis provides
7 strong evidence that perineal talcum powder product
8 use causes ovarian cancer. Strong here does not
9 pertain to the size of the odds ratio/relative risk.
10 Rather, it refers to the fact that the number of cases
11 included was larger than any previous study. The
12 eight-case-control studies included showed similar
13 effect sizes for association of genital powder use and
14 ovarian cancer risk consistency."

15 This the part I want to focus on.

16 "The dose-response effect was clear and there
17 were enough numbers of cases to determine effects on
18 subtypes of ovarian cancer."

19 I read that right?

20 A. Yes.

21 Q. The opinion is based in part on your conclusion
22 that the study showed a clear dose-response effect.
23 Right?

24 A. Yes.

25 Q. Terry 2013 pooled eight case control studies.

1 Correct?

2 A. Yes.

3 Q. The data from five of those case-control studies
4 were previously published -- meaning published in a
5 different paper -- before they were mentioned in Terry
6 2013's pooled analysis. Correct?

7 A. Yes.

8 Q. And you wrote that in your report. You made
9 that precise statement that the data from five of the
10 studies were previously published, but that three were
11 not previously published?

12 Do you remember that?

13 A. Yes.

14 Q. In this litigation -- and I mean in your report
15 for this litigation -- you define a pooled analysis --
16 and this is page 22 of your report, Exhibit C 7, first
17 full paragraph, first sentence -- you defined a pooled
18 analysis as "a type of meta-analysis where original
19 individual level data from various published and/or
20 unpublished epidemiological studies are combined and
21 reanalyzed."

22 Did I read that right?

23 A. Yes.

24 Q. Now, Terry 2013, which included previously
25 unpublished talc data from three case control studies

1 fits the description of a pooled analysis in your
2 litigation report here. Right?

3 A. Yes.

4 Q. So in relying on Terry 2013 as part of the
5 science relating to use of talcum powder and risk of
6 ovarian cancer, you relied on the data from those
7 previously unpublished studies. Correct?

8 A. I relied on the data on the eight studies that
9 included those three unpublished, yes.

10 Q. Now, let me pull up your report again. There is
11 one citation there, citation No. 39. There is one and
12 only one citation there. Correct? There is just
13 citation for that proposition. Correct?

14 A. I'm trying to find my report.

15 Q. I'll represent to you that is the Terry study.
16 Will you take my representation?

17 A. Okay.

18 Q. I would like to pull up your definition again of
19 what a pooled analysis is.

20 MR. WILLIAMS: If we could put that up, page
21 22, C-7.

22 Q. Looking at the first two sentences there, you
23 cannot point us to any referenced material that you
24 have reviewed anywhere that describes a pooled
25 analysis, using the words that you set forth here in

1 your report. Correct?

2 A. I'm not sure. There have been methods, papers
3 written about pooled analyses. I'm not sure if
4 they -- I'm not sure if they use these particular
5 concepts.

6 Q. You wrote these two sentences here on page 24 of
7 your report, correct, defining a pooled analysis?

8 A. It is in my report, yes.

9 Q. My question was a simple one; it was -- can you
10 point the Court to any reference material that you
11 have reviewed that describes a pooled analysis, using
12 those words, with particular reference to published
13 and/or unpublished epidemiological studies?

14 A. I know that I did not cite -- I did not cite
15 Friedenreich 1993 as a description of pooled analyses.
16 And I did not cite that in my report. I did use World
17 Cancer Research Fund methods description in my report
18 that's cited not here but cited overall in the report.

19 Q. Now, the Friedenreich paper 1993 is not
20 referenced in your report?

21 A. It is not in my report.

22 Q. Let's talk about the World Cancer Research Fund
23 document. It has already been discussed, Exhibit A
24 153, the "judging the evidence" report that you, your
25 colleagues published in 2018, just last year.

1 A. But this report --

2 Q. There is no question pending.

3 Let's take it one step at a time.

4 Please turn to page 12 of Exhibit 153. Do you
5 have that in hand.

6 A. On the -- yes.

7 Q. On the right-hand side of that page, do you see
8 a definition of "pooled analysis" that is contained in
9 the report? Do you see that?

10 A. Yes.

11 Q. Here you and your colleagues wrote:

12 "Pooled analysis is a type of meta-analysis in
13 which original individual level data from various
14 published epidemiological studies of a similar type,
15 usually prospective cohort studies, are combined and
16 reanalyzed."

17 Did I read that right?

18 A. Yes.

19 Q. It goes on and says:

20 "The combination of data from multiple studies
21 creates a larger data set and increased statistical
22 power."

23 Right?

24 A. Yes.

25 Q. The sentence also includes the phrase "of a

1 similar type, usually prospective cohort studies."

2 Do you see that?

3 A. Yes.

4 Q. So in the World Cancer Research Fund definition
5 of a "pooled analysis," it references studies of a
6 similar type, usually prospective cohort studies.

7 Right?

8 A. Yes, it says that.

9 Q. Let's look at the version of your report.

10 In your report you wrote:

11 "Pooled analysis is the type of meta-analysis
12 where original individual level data from various
13 published and/or unpublished epidemiological studies.
14 The definition in the World Cancer Research Fund does
15 not say and/or unpublished."

16 Can we agree?

17 A. Yes.

18 Q. And your definition in your report at page 22
19 does not include the language that was included in the
20 World Cancer Research Fund of a similar type, usually
21 prospective cohort studies. Right?

22 A. Correct.

23 Q. Now, did the members of the World Cancer
24 Research Fund have your report at the time this study
25 came out? This paper from WCRF came out in 2018.

1 A. No.

2 Q. You did have the WCRF paper at the time you
3 wrote your report for this matter. Right?

4 A. Yes.

5 Q. And you personally typed up your paper.
6 Correct?

7 A. Yes.

8 Q. And when you typed it up, you added "and/or
9 unpublished." Right?

10 A. I included those words, yes.

11 Q. And you took out a similar type, usually
12 prospective cohort studies. Right?

13 A. Those words are not in my version, yes.

14 Q. The reason that you added "and/or unpublished"
15 was that you knew that the study that you were relying
16 upon with its pooled analysis included data from three
17 studies that were unpublished. Right?

18 A. I don't think so. Pooled analyses, they're
19 pooling projects that begin with no published studies.
20 The pooled analysis I collaborated in began with us
21 providing data to investigators, some of which had
22 been published, some not. The NCI funds many pooling
23 projects. Pooling projects can be with randomized
24 control trials. It is very common. Pooling projects
25 have been with case control studies. One of my

1 pooling projects was case-control studies. One of my
2 projects was a pooling study of randomized trials. My
3 statement in the report needed to be more general than
4 what WCRF indicated.

5 Q. Let's go to your report C-7, page 8, first full
6 paragraph, your description of the Terry pooled
7 analysis. What you wrote in your report was the
8 pooled analysis which included data from five
9 previously published and three unpublished
10 case-control studies.

11 And you went on."

12 That's what you wrote?

13 A. Yes.

14 Q. And the reason you took this part out in the
15 description of a pooled analysis -- and by "this
16 part," I'm referring to the words "of a similar type
17 usually prospective cohort studies," is that you knew
18 if the definition of pooled analysis that you and your
19 colleagues used for the WCRF had been applied to this
20 case, it would have focused the Court on the
21 prospective cohort studies, none of which has found an
22 association between talc use and ovarian cancer.

23 Is that true?

24 A. No.

25 Q. Do you deny you added the words "and/or

1 unpublished" and removed the words "of a similar type
2 usually prospective cohort studies" when you wrote the
3 definition of "pooled analysis" in your report?

4 A. I agree many of the words are the same. This is
5 an epidemiologic concept. If I were to write what the
6 WCRF definition says in some other context, it would
7 not be correct because it is not true that only cohort
8 studies are done for pooled analyses.

9 Pooled analyses -- as I mentioned, my first
10 pooled analysis was years before 2016. It was
11 20 years before, which was case-control studies. My
12 second pooled analysis was a couple of years before
13 2016. That was randomized control trials. I also
14 participated in cohort study pooled analysis, and
15 published from that. And so it is a very general type
16 of epidemiology. It's not limited to cohort studies.

17 So it would be incorrect for me to say
18 "usually prospective cohort studies" because that is
19 not the case. And for published and/or unpublished, I
20 didn't want to leave a statement that says "original
21 individual data from published epidemiologic studies"
22 because that is not the case. In some pooled projects
23 there will be published and unpublished data, and that
24 has been true in my studies and many other pooled
25 projects.

1 Q. Did you understand my last question to be
2 suggesting your definition of a pooled analysis from
3 the WCRF paper said only prospective studies?

4 I read it accurately and said "usually
5 prospective cohort studies," I read that correctly;
6 didn't I?

7 A. Even the word --

8 Q. One question at a time.

9 Did I read it correctly or not? I said
10 "usually and not only." Right?

11 A. It sounds like that's what you said, yes.

12 Q. My point is, if you had focused your attention
13 on the prospective studies for purposes of this
14 matter, then the definition that you and your
15 colleagues used for the WCRF would have hurt the
16 plaintiffs in this case; would it not?

17 MS. PARFITT: I object.

18 MR. WILLIAMS: Hurt the plaintiffs' position.

19 THE COURT: Thank you.

20 BY MR. WILLIAMS:

21 Q. Do you understand my question?

22 A. My purpose in writing it was to be complete
23 about the methodology, and it didn't occur to me what
24 would help one side or the other when I wrote my
25 methodology.

1 Q. In both definitions, the one in the WCRF paper
2 and in your report here, the next sentence appears
3 word-for-word. Right? The combination of data from
4 multiple studies creates a larger data set and
5 increased statistical power. Correct?

6 A. Yes.

7 Q. Let me ask you some questions on dose-response,
8 please.

9 On the question of dose-response, -- that is,
10 whether the studies you reviewed showed or did not
11 show an increasing risk of ovarian cancer from
12 increased talc use -- you agree that not all of the
13 studies on that list of the 28 studies, looked into
14 that question. Right?

15 A. Correct.

16 Q. Of the studies that did look into dose-response,
17 not all of those studies found a dose-response.
18 Right?

19 A. Correct.

20 Q. Some purported to find a trend; some did not.
21 True?

22 A. Correct.

23 Q. So just on that question, the question of
24 whether or not the studies that looked at
25 dose-response found a trend, the studies reached

1 inconsistent results. True or not. True?

2 A. True.

3 Q. Your opinion in this litigation is that
4 cumulative exposure, meaning frequency of genital talc
5 use, how often one uses it, and duration or times
6 duration, meaning years of talc use is the optimal
7 metric of dose-response effects. Right?

8 A. Yes.

9 Q. You agree, though, not all studies examining the
10 cumulative dose-response found a trend or a
11 dose-response. Correct?

12 A. When you say "trend," maybe you can define that.

13 Q. Sure.

14 For purposes of my question, please focus on
15 those studies that examined what you call cumulative
16 dose-response, meaning cumulative use, frequency times
17 duration. Do you have that subset in mind?

18 A. Yes.

19 Q. With those studies that did use that type of
20 calculation, some purported to find a dose-response
21 and some did not. Right?

22 A. Correct.

23 Q. So on that question, the question of whether or
24 not the studies that looked at a cumulative use found
25 a dose-response, on that question, the studies reached

1 inconsistent results. Right?

2 A. Correct.

3 Q. Let's go to Terry A 139. I'll direct your
4 attention to page 8, the right-hand column, first full
5 paragraph about midway down. I'm looking for the
6 sentence that begins "although":

7 The authors wrote:

8 "Although a significant increase in risk with
9 an increasing number of genital powder applications
10 was found for nonmucinous epithelial ovarian cancer,
11 when non-users were included in the analysis, no trend
12 in cumulative use was evident in analyses restricted
13 to ever users of genital powder."

14 That's what the authors wrote in their study.
15 Correct?

16 A. That's what they wrote, yes.

17 Q. The question of whether a trend in cumulative
18 use was evident in Terry, you've come to an opposite
19 conclusion to the conclusion of the authors of that
20 study with respect to ever-never use?

21 A. I think they are not talking about ever/never
22 use but dose-response.

23 Q. I'm talking about a dose-response effect when
24 the analysis is restricted to people who actually used
25 talcum powder.

1 A. Only users.

2 Q. Correct.

3 A. The first part of that sentence says, "although
4 a significant increase in risk with an increasing
5 number of genital powder applications was found for
6 nonmucinous, epithelial ovarian cancer when non-users
7 were included in the analysis."

8 This is the issue, and I talked about it this
9 morning. When non-users with a comparison -- which is
10 a very valid comparison, there was a statistically
11 significant p-Value. When they were not included,
12 when it was only the users compared among themselves,
13 the p-Value was .17. Those are the two different
14 statistical tests I look at. I also look at the
15 confidence intervals for each of those levels.

16 Q. Let me focus you on the part I was trying to
17 focus you on. I was trying to focus you on A 139,
18 page 8. The part I was trying to focus you on is the
19 part after the comma. It goes on and says:

20 "No trend in cumulative use was evident in
21 analyses restricted to ever users of genital powder."

22 That's what they said. Correct?

23 A. Yes.

24 Q. And just for clarification, the issue here is
25 whether or not in calculating a dose-response the

1 authors of a study include in the calculation of
2 dose-response people who never used talc at all.

3 Right?

4 A. Yes.

5 Q. You say for purposes of this matter and for
6 purposes of emphasizing that Terry in your view shows
7 dose-response. You say that the people who never used
8 talc should be included in the calculation. Right?

9 A. Yes. Although I think it is very appropriate
10 they did it both ways.

11 Q. And what the author said was that there was no
12 trend if you focused only on people who actually used
13 talc, and then watched what happened if they used more
14 and more over their lifetimes. Fair?

15 A. Yes. And they also reported when they included
16 non-users.

17 Q. They reported it both ways. Right?

18 A. Yes.

19 Q. You said I think earlier today something to the
20 effect of statisticians favor including those who
21 never used the product, did you say something to that
22 effect?

23 A. That's my understanding, that unless there is
24 some other reason to exclude non-users, it is
25 appropriate to include them.

1 Q. What is that understanding based on?

2 A. That it's appropriate to include non-users when
3 you are looking at a dose-response effect, unless
4 there is some other reason non-users are so different
5 they should be excluded. I liken it to if you are
6 testing a dose for effectiveness in a randomized
7 trial, you would compare to placebo.

8 Q. If you are testing the effect of a dose, there
9 should a dose. Right? This is a crude example. If
10 someone were testing the effect of drinking beer, you
11 would test the effect of one can of beer versus the
12 effect of 10 cans of beer. You wouldn't necessarily
13 include zero cans of beer?

14 A. I think you would. We note the test of trends
15 that were -- the two tests of trends we're both
16 referring to are the tests including relative risk.
17 These relative risks were calculated comparing to the
18 non-users.

19 Q. You said earlier today there was some basis --
20 strike that.

21 You said earlier today that statisticians
22 prefer to include people who never used the substance.
23 Tell the Court the basis for that.

24 Can you cite some periodical or study to that
25 effect.

1 A. Dr. Sander Greenland, and I don't have the
2 article on the top of my head.

3 Q. Anything else?

4 A. That would be the reference I have.

5 Q. Are you familiar with an epidemiologist named
6 Britton Trabert.

7 A. He's an epidemiologist?

8 Q. I believe so, or statistician, one or the other?
9 You don't know the name?

10 A. I don't.

11 Q. Let me show you an article and see if you have
12 seen it.

13 Britton Trabert is a woman. I beg your
14 pardon?

15 This is a commentary entitled:

16 "Body powder and ovarian cancer risk, what is
17 the roll of recall bias?"

18 Authored by Britton Trabert. It is dated
19 2016. Have you ever read this article before?

20 A. No, it doesn't look familiar.

21 Q. Let me direct your attention to the lower
22 right-hand corner of the right-hand column on page --
23 the first page of the document, which we will mark as
24 McTiernan 521. It says at the bottom of the page,
25 quote:

1 "In addition, when a pronounced binary
2 association is present use of the never or no category
3 in assessing trend can induce a trend where none
4 exists. The recent OCAS analysis reported no trend
5 with increasing lifetime application when restricted
6 to talc users." And it has a citation to note 18.

7 Do you see that? And that citation is to the
8 Terry paper.

9 A. Yes.

10 Q. Now, you would agree that if the people who did
11 not ever use talc are excluded from the analysis of
12 the dose-response, the conclusion of the Terry paper
13 was that there was no significant dose-response.
14 Right?

15 A. My conclusion would be that the p-Value is .17
16 but the relative risks still remain the same. They
17 increase with increasing dose over the four
18 categories.

19 Q. There was no significant trend if the people who
20 never used talc were excluded from the calculation.
21 Right?

22 A. The trend was not statistically significant,
23 correct.

24 Q. Which means that there was no association that
25 you could establish. Correct?

1 A. It doesn't change the relative risk.

2 Q. Let's talk about the Penninkilampi study as it
3 relates to -- actually, not that one. Let's do
4 another one.

5 Let's talk about the Harlow paper.

6 A. Which one is this?

7 Q. It is 1992. It is Exhibit A 55.

8 Do you remember that Harlow 1992 was one of
9 the papers that did use the metric that you say is
10 proper, which is frequency times duration? That's
11 true. Correct?

12 A. Yes.

13 Q. Turn to page 8, left-hand column, the first full
14 page. It says:

15 "As a continuous variable in a multi variate
16 model, no significant dose-response was observed
17 between total genital applications of talc and ovarian
18 cancer risk." Correct?

19 A. Yes, it states that.

20 Q. One of the other studies you reviewed is Cook
21 1997. This is Exhibit A 21?

22 This is one of the studies you read. Right?

23 A. Yes.

24 Q. Your conclusion in your report, if we could call
25 up Exhibit C 7 at page 71 in the chart, that you had

1 in the back of your report, you listed Cook as a study
2 where there was no cumulative lifetime days,
3 therefore, no dose-response. Is that right, Doctor?

4 A. I think what that means is no dose-response
5 found and that was the matrix she looked at cumulative
6 lifetime days.

7 Q. Let's take a look at the study then. Exhibit A
8 21 in your book is the Cook study. Let me ask you to
9 go there. Please turn to page 6, Table 3. Do you see
10 there is a table where the study includes
11 dose-response?

12 A. Yes.

13 Q. And it has information based on cumulative
14 lifetime days of any perineal dusting. Correct?

15 A. Yes.

16 Q. It says:

17 "Any perineal dusting," and it looks at less
18 than 2,000 lifetime days going up to over 10,000
19 lifetime days, and it lists the results. Correct?

20 A. Correct.

21 Q. And so at less than 2,000 lifetime days it is
22 1.8 risk ratio. Right?

23 A. Yes.

24 Q. And then if people use more talc for between
25 2,000 and 5,000 lifetime days, the risk ratio goes

1 down. Agreed?

2 A. Yes.

3 Q. And the risk ratio goes down for people who use
4 more talc between 5,000 and 10,000 lifetime days.
5 Right?

6 A. Yes.

7 Q. If they use more than 10,000, it goes up again.
8 Right?

9 A. Yes.

10 Q. That would have been kind of an upside down U if
11 one were to plot it on a graph. Right?

12 A. Yes.

13 Q. Did that refresh your memory that the Cook study
14 did not in fact find a dose-response?

15 A. Yes. And that's what I indicated in that table.

16 Q. I thought you were saying you were not sure
17 that's what you indicated in the table?

18 A. If I put the word "no" and "no dose-response,"
19 and that the metric is what was in parenthesis.

20 Q. Let's look at Cramer 19 -- actually, let's look
21 at your table first. It is Exhibit C 7. That's your
22 report of the table, in the back, is page 70, a
23 similar table we used before.

24 Actually, that's not the right one. We're
25 looking for the entry that says "no lifetime

1 applications." It is page 70, Table 1, Cramer 1999
2 entry.

3 What you wrote here with respect to
4 dose-response for Cramer is:

5 "Yes, there is dose-response lifetime
6 applications when Fallopian tubes present with an O.R.
7 for less than 3,000 uses of 1.54 and more than 10,000
8 1.72 as the RR -- excuse me -- between three and
9 10,000 1.72 and for more than 10,000 1.80."

10 That's what you cited. Right?

11 A. Yes. The only correction is "patent" instead of
12 "present."

13 Q. Now, on this one you did not list a p-Value or
14 say anything about statistical significance, as you
15 did with the Harlow study a few minutes ago on your
16 chart. Correct?

17 A. Correct, it is not there.

18 Q. You accurately just stated there is no p-Value
19 listed on your chart because they did not calculate
20 one. Is that right?

21 A. I don't know. I would have to look at the
22 study.

23 Q. Will you take my representation that --

24 A. Yes.

25 Q. Where in Table 1 can we tell whether the

1 dose-response data that you chose to include here is
2 for genital talc use as opposed to, for example, non-
3 genital use? Can we tell from reading your chart?

4 A. Can you tell me which number the paper is?

5 Q. It is A 23. Exhibit A23 is Cramer 1999. I'll
6 direct your attention in that exhibit to page 5, Table
7 3. Do you have that in front of you?

8 A. Yes.

9 Q. Now, what you reported in your chart that was in
10 the report provided to the Court was that in this area
11 here in Table No. 3 --

12 MR. WILLIAMS: For the record, I'm focusing on
13 the portion that says "applications censored."

14 Q. You were referring to the fact that if one used
15 talc less than 3,000 times, the risk ratio was lower
16 than if one used it more than 10,000 times. This
17 portion I'm indicating with the laser. Correct?

18 A. Yes.

19 Q. There was another chart for total applications
20 here that listed for people who are using genital
21 talc. It lists less than 3,000 uses a risk and odds
22 ratio of 1.84. Correct?

23 A. Yes.

24 Q. An odds ratio for 3,000 to 10,000 uses of 1.43.
25 Correct?

1 A. Yes.

2 Q. And an odds ratio of more than 10,000 uses of
3 1.43. Correct?

4 A. Yes.

5 Q. That odds ratio goes down not up with more uses.
6 Correct?

7 A. Correct.

8 Q. You could see here this sets forth a p-Value
9 which is 0.472. Correct?

10 A. Yes.

11 Q. And that p-Value is more than .05. Right?

12 A. Yes.

13 Q. Which means it is not statistically significant.
14 True?

15 A. Yes.

16 Q. You chose to use this trend, this set of values,
17 that includes nongenitally exposed people. Right?

18 A. I believe I did not put a p-Value in the table.
19 I didn't include either one of those p-Values. That's
20 why I was confused why I had nothing there.

21 Q. What you included in the table, Doctor, was a
22 statement that this Cramer 1999 showed, yes, a
23 dose-response, and then you simply listed the date
24 that appears here under the applications censored
25 group for people including folks who did not use talc

1 in the genital area; they used it elsewhere. Right?

2 A. Yes. If I had room in the table, I would have
3 put the relative risk and the confidence intervals and
4 did the p-Value. I would have focused on the genital
5 exposure patients. The issue is, though, I don't know
6 what those RRs referred to, and so I would need to
7 look back at the paper to see that. It looks like
8 they are not giving full data of genitally exposed --

9 Q. Can we agree, Doctor, if you had focused the
10 Court on the total application PSC data for people who
11 used talc only in the genital area, that you would not
12 have been able to report to the Court that there was a
13 dose-response because there wasn't?

14 A. But there is in the bottom one, where it is
15 called "pelvic censored," and that is people who had
16 patent Fallopian tubes, and there is some science, the
17 case-control studies, particularly suggesting the risk
18 is greater in people who have patent Fallopian tubes
19 so that the material can move up. If I had room, I
20 could have put both in there.

21 Q. You can't tell the Court what happens to the
22 statistical significance in the bottom group, the
23 pelvic censored group, when the nongenitally exposed
24 women are excluded; right? You can't do that?

25 A. They gave the p-Values. They provided it. It's

1 the relative risk that now I'm saying I can't. But
2 there is a dose-response you can see with confidence
3 intervals that do not include one. The question is
4 which group are those referring to. But my statement
5 is correct. There is a dose-response in that group.

6 Q. Right here in the portion that relates to people
7 who actually used talc in the perineal area, there is
8 data under "total applications" that does not have a
9 statistically significant result. Correct?

10 A. If you look at patent, which I've stated on the
11 table, then you see that.

12 Q. Just a yes or no if you can give it. There is
13 data on this table for total applications that
14 includes people who use talc in the perineal area, and
15 that does not show dose-response. True or not true?

16 A. If I reported on that table, I would say that,
17 but I reported on the other table.

18 Q. And the answer is yes?

19 A. The question again was?

20 Q. I'll move on.

21 Let's go to a study called Mills 2004. This
22 is a retrospective case-control study by Mills. You
23 reviewed this data. Correct?

24 A. Yes.

25 Q. Please take a look at page 4, Table II. This is

1 Exhibit A 94. This includes data on dose-response.

2 Correct?

3 A. Yes.

4 Q. And there is a portion that talks about
5 cumulative use frequency times duration. Right?

6 A. Yes.

7 Q. It include never users?

8 A. Yes.

9 Q. It include four different quartiles. Correct?

10 A. Yes.

11 Q. And it lists in the right-hand column odds
12 ratios for each of those quartiles. Correct?

13 A. Yes.

14 Q. The first quartile, meaning the lowest exposure
15 calculated using the metric you say is the best one
16 frequency times duration, it reports 1.03 as the point
17 estimate. Correct?

18 A. Yes.

19 Q. And that value is not statistically significant.
20 Correct?

21 A. Yes.

22 Q. The second quartile people who use more talc
23 than people in the first quartile, the result is 1.81
24 statistically significant. Right?

25 A. Correct.

1 Q. The third quartile goes down. That's for people
2 who used more talc than those in the first two
3 quartiles. True?

4 A. Correct.

5 Q. It goes down to 1.74. Right?

6 A. Correct.

7 Q. And for people who are have the highest exposure
8 which is who reported the most use calculated by
9 frequency times duration, the odds ratio is 1.06. Not
10 statistically significant. Correct?

11 A. Correct.

12 Q. This study does not show a dose-response.
13 Correct?

14 A. I agree. That's what I indicated in my table.

15 Q. Right. In your table, if you add them all up --
16 I'm not going to ask you to do it now. It will take
17 too long -- there are a number of studies that analyze
18 frequency times duration that show no dose-response
19 and some that purport to show a dose-response. Is
20 that right?

21 A. I haven't added it recently. I did it for my
22 report, but I don't know the exact numbers.

23 Q. I'm not asking you to add right now. There are
24 some that show a dose-response and some that do not.

25 A. Correct.

1 Q. We have talked about the Terry study and your
2 conclusions there and your calculations. Right?

3 A. Yes.

4 Q. That is one of the ones you said showed
5 dose-response. True?

6 A. Yes.

7 Q. We talked about Cramer 1999. That's another you
8 said showed a positive dose-response. True?

9 A. Yes.

10 Q. Let's move on.

11 The most thorough case-control studies in your
12 opinion were those that differentiated among different
13 areas of exposure to talc.

14 A. Are you citing something in my report?

15 Q. I am.

16 A. I want to see what it refers to.

17 Q. By areas of exposure, I mean perineal use. One
18 area of exposure is the use of talcum powder products
19 on the diaphragm. Correct?

20 A. Correct.

21 Q. Please turn to the Cramer 2016 study we marked
22 earlier. It is A 25. Do you have that in front of
23 you?

24 A. Yes.

25 Q. Table 1 is entitled type, "Timing and Duration

1 of Genital Talc Use." Right?

2 A. Yes.

3 Q. It lists potential exposure in women with no
4 personal use. Right?

5 A. Yes.

6 Q. And it pulls out diaphragm only use. Correct?

7 A. Correct.

8 Q. And we're talking about diaphragms that have
9 some sort of talc on them. Right?

10 A. Is that how they define it?

11 Q. Let's look at what the data shows.

12 A. I want to see how they asked -- I want to check
13 how they are asking about the diaphragm use.

14 I see, yes, they have that.

15 Q. That's the reason why it would be relevant
16 because if a woman had talc on her diaphragm and
17 inserts the diaphragm, it is closer to the ovaries
18 than if a woman dusts herself outside, say, in her
19 panties. Correct?

20 A. It did not ask if they rinsed it off prior to
21 applying spermicidal jelly, so we don't know about
22 talc from that question.

23 Q. What the results indicated were that people who
24 used the diaphragm, and that was their exposure to
25 talc, the odds ratio was 0.73 with a statistically

1 insignificant confidence interval of 0.57 to 0.93.

2 Correct?

3 A. No. The traditional interpretation of a
4 confidence interval is where it includes 1. This does
5 not.

6 Q. It does not include 1?

7 A. So that would suggest statistical significance
8 around that odds ratio.

9 Q. I beg your pardon. Because the odds ratio is
10 below 1, and because the confidence interval does not
11 hit 1.0, this is statistically significant?

12 A. Yes.

13 Q. So the result is a statistically significant
14 finding of a protective effect for the use of a
15 diaphragm with talc on it. Correct?

16 A. Yes. With the caveat we don't know if the woman
17 rinsed the diaphragm before putting spermicidal jelly
18 and before inserting. So we don't know about the
19 amount of real exposure.

20 Q. Are we assuming every woman in the study --

21 A. Some women would have been instructed to do it
22 that and some not.

23 Q. You know that the study did not do that?

24 A. I don't know that they asked about whether they
25 rinsed it or not.

1 Q. You don't know one way or the other they did?

2 A. Right.

3 Q. But we do know there is a statistically
4 significant finding of a protective effect, meaning if
5 the epidemiological evidence is credited, it would
6 mean if the women used the diaphragm with talc on it,
7 she would have a lower chance of getting ovarian
8 cancer. Correct?

9 A. If there was talc on it. That's what we don't
10 know.

11 Q. Let me have you look at the Berge study, the
12 2018 meta-analysis. This is one of the studies you
13 said was excellent. Right?

14 A. Which number is this?

15 Q. A 11. I'll direct you to Table II on page 7.
16 Do you have that there?

17 A. Yes.

18 Q. This study, one of the ones that you say was
19 excellent in terms of its methodology, lists with one
20 of its findings for the use of a diaphragm a
21 statistically significant protective effect odds ratio
22 of 0.75 with a confidence interval that does not cross
23 1, 0.73 on the low end to 0.88 on the high end.
24 Correct?

25 A. Yes.

1 Q. Please turn to the Penninkilampi study. That's
2 Exhibit A 109. Please look at page 5.

3 Page 5 has a table, Table 1, that like the
4 other studies we just looked at, references diaphragm
5 use. Correct?

6 A. Yes.

7 Q. And it references the method of talc use
8 suggesting talc was on the diaphragm. Right?

9 A. Yes.

10 Q. This one is not statistically significant
11 because it crosses 1.0. Correct?

12 A. Yes.

13 Q. But the finding was 0.84 as the odds ratio.
14 Correct?

15 A. Yes.

16 Q. So if it had been statistically significant,
17 like the other two studies we just looked at, it would
18 have had a protective effect. Correct?

19 A. Yes.

20 Q. Earlier today you testified on direct
21 examination that an odds ratio of 1.4 is -- strike
22 that.

23 You testified an odds ratio of 1.4 has in the
24 past sufficed for purposes of findings there is a
25 causal connection between a substance and some

1 disease. Correct?

2 A. I don't recall talking about causality. I
3 recall talking about some additional risk factors in
4 the low range.

5 Q. You talked about HRT, did you not?

6 A. Yes.

7 Q. Let's take a look at your report and what it
8 said about HRT. That's hormone replacement therapy,
9 for the record. That's Exhibit C 7, page 26. Is that
10 the portion of your report?

11 Doctor, that references HRT?

12 A. Yes.

13 Q. There is a sentence that starts at the bottom of
14 26 and carries over; and at the end of that sentence
15 it has a citation to number 55, reference number 55.
16 Correct?

17 A. Yes.

18 Q. If you go to page 80 of your report -- let's
19 look at that reference. Do you have that in front of
20 you?

21 A. Yes.

22 Q. That reference 55 is to a study written by
23 Rossouw. It is from 2002. Correct?

24 A. Yes.

25 Q. This was a study you cited talking about the

1 principal results from the Women's Health Initiative
2 Randomized Control trial. Right?

3 A. Yes.

4 Q. So with respect to HRT, a randomized control
5 trial had been conducted that showed the association.
6 Right?

7 A. Yes.

8 Q. There hasn't been a randomized control trial,
9 nor could there be, in your view, for talcum powder?

10 A. That's correct.

11 Q. It goes on on the next sentence at the top of
12 page 27. The sentence says:

13 "A meta-analysis of clinical trials and
14 observational studies in 2018 found that use of this
15 therapy increased risk of breast cancer by
16 59 percent."

17 Did I read that right?

18 A. Yes.

19 Q. And it cites item 56. Correct?

20 A. Yes.

21 Q. Let's turn to page 80 and see what item 56 is.
22 That was a study by Kim dated 2018. Correct?

23 A. Yes.

24 Q. It says:

25 "Menopausal Hormone Therapy and the Risk of

1 Breast Cancer By histological Type and Race: A
2 Meta-Analysis of Randomized Controlled Trials and
3 Cohort Studies."

4 Did I read that right?

5 A. Yes.

6 Q. So here there were not only randomized trials
7 but there were cohort, forward-looking cohort studies
8 with respect to HRT. Right?

9 A. Yes.

10 Q. That's very different than the situation before
11 Her Honor, is it not?

12 A. In terms of?

13 Q. In terms of whether or not there have been
14 randomized control trials. Right?

15 A. Correct.

16 Q. What you are focusing on for purposes of your
17 testimony is case-control studies and cohort studies.
18 Correct?

19 A. Yes.

20 Q. But the cohort studies for our purposes are all
21 studies that find no statistically significant
22 association between the use of talc and ovarian
23 cancer. True?

24 A. Correct.

25 Q. Let me ask you some questions on confounding.

1 For the talc studies that presented both adjusted and
2 unadjusted risk ratios, your opinion is that those
3 studies found little effect of confounding variables.
4 True?

5 A. Yes. For the studies that showed both the
6 unadjusted odds ratios and the adjusted odds ratios,
7 nine out of 10 of them had very similar results.

8 Q. You believe that all, all except for one of the
9 talc studies that you reviewed performed adjustments
10 for several potential confounding variables?

11 A. Yes.

12 Q. And you agreed this morning or you stated this
13 morning on direct examination with plaintiffs'
14 counsel, you said that your systematic analysis
15 examined whether or not a study adjusted for
16 confounding. Do you remember saying that?

17 A. Yes.

18 Q. But the truth is, Doctor, that you did not
19 actually look at the specific confounding or
20 confounders for each of those studies. Right?

21 A. I did look at the tables in which they indicated
22 confounders. They were different in each study. I
23 assumed that they reported the ones that they adjusted
24 for.

25 Q. You did not look at the specific confounders for

1 each of the studies?

2 A. I did look at confounders. I read through the
3 tables and list of variables they listed.

4 Q. Please take a look at your deposition, page 175,
5 line 25 to 176, line 16:

6 "QUESTION: Without reviewing the study, are
7 you able to tell us, as you sit here, how many of the
8 case-control studies you read and reviewed and are
9 relying on in this case do not adjust for body mass
10 index?

11 "ANSWER: No, I did not count that.

12 "QUESTION: Why not?

13 "ANSWER: I was tasked to look at the overall
14 association. I did not look at specific confounders
15 for each of the studies."

16 That was your testimony. Right?

17 A. I see what you mean. For my expert report, I
18 did not go through and mark for which studies adjusted
19 for BMI and which did not, but I did look at the
20 studies to see what variables they adjusted for as I
21 reviewed them.

22 Q. My question was whether I read correctly your
23 testimony. Did I do that?

24 A. To me it looks like the testimony you were
25 asking then was about body mass index, BMI.

1 Q. Did I read it correctly? Was that your
2 testimony?

3 A. I'm not sure which section you are talking
4 about.

5 THE COURT: He's not asking you to comment
6 upon. He wants to know what he read to you, was that
7 accurate? What he read, does that appear in the
8 transcript you testified to?

9 THE WITNESS: Yes.

10 BY MR. WILLIAMS:

11 Q. One of the items that you placed on your bases
12 for finding a causal association between talc use and
13 ovarian cancer, you referenced IARC. Right?

14 A. Yes.

15 Q. And you are familiar with that agency because
16 you've done work for them. Right?

17 A. Yes.

18 Q. You know that IARC has five different categories
19 into which it places substances. Right?

20 A. Yes.

21 Q. Group 1 is substances that IARC believes are
22 carcinogenic to humans. Right?

23 A. Yes.

24 Q. Group 2 A is for substances IARC believes are --
25 probably carcinogenic. Right?

1 A. Yes.

2 Q. Group 2 B is for substances that IARC believes
3 are possibly carcinogenic. Right?

4 A. Yes.

5 Q. Group 3 is for substances that are not
6 classifiable. Right?

7 A. Yes.

8 Q. And Group 4, finally, is for substances IARC
9 believes are probably not carcinogenic. Right?

10 A. Yes.

11 Q. You know, there is only one substance that has
12 ever been placed in Category IV?

13 A. I knew it was very small.

14 Q. In 2006 IARC listed perineal use in the 2-B
15 category. Correct?

16 A. Yes.

17 Q. That's 2-B, possible carcinogenic. Right?

18 A. Yes.

19 Q. Please take a look at the IARC monograph. It is
20 Exhibit A 72 K. It is a really long document. Sorry
21 about the length. I would like you to look at page 46
22 of the 2010 IARC monograph on talc.

23 Do you have that in front of you?

24 Using the numbers at the bottom of the page,
25 page 46. It's also on the board. See there is a

1 reference to Group 2 B?

2 A. Yes.

3 Q. And this category is used for agents for which
4 there is "limited evidence of carcinogenicity in
5 humans and less than sufficient evidence of
6 carcinogenicity in experimental animals."

7 Do you see that?

8 A. Yes.

9 Q. Please turn now to page 42, a few lines earlier.
10 The term "limited evidence of carcinogenicity" is a
11 defined term in the monograph. Correct?

12 A. Yes.

13 Q. There is a definition at the bottom of this
14 page, page 52, for "limited evidence of
15 carcinogenicity." Right?

16 A. Yes.

17 Q. The definition is:

18 "A positive association has been observed
19 between exposure to the agent and cancer for which a
20 causal interpretation is considered by the working
21 group to be credible, but chance, bias, or confounding
22 could not be ruled out with reasonable confidence."

23 Right?

24 A. That's what it says, yes.

25 Q. So IARC was saying it could not rule out chance

1 or luck with respect to talcum powder use, perineal
2 use, and ovarian cancer. Correct?

3 A. At the time when they reviewed the data which I
4 believe was about 2008. So 10 years ago.

5 Q. This is the IARC monograph from 2010, but they
6 looked at the data before that. Right?

7 A. Yes.

8 Q. IARC was also saying that it could not rule out
9 bias. Right?

10 A. Yes.

11 Q. You understand that to mean recall bias.
12 Correct?

13 A. It could be any bias.

14 Q. And IARC was also saying it could not rule out
15 confounding factors. Correct?

16 A. Correct.

17 Q. Now, IARC has never moved perineal talc up to a
18 higher classification than Group 2 B. Right?

19 A. But they are going to reconsider it. They
20 classified it as high priority for review again.

21 Q. Do you have any knowledge one way or the other
22 how many items are listed on that elevated interest
23 list?

24 A. It is a minimal number. I believe we added that
25 to the list.

1 Q. Do you know how many?

2 A. I believe we added that to the list of items.

3 Q. Let me ask you this: As of today at this point
4 in time when the Court is assessing whether or not
5 sufficient evidence exists to say that talc causes
6 ovarian cancer, as you have opined, IARC still lists
7 perineal talc use as a Group 2 B substance. Correct?

8 A. They have not reviewed it again yet.

9 Q. The answer is yes?

10 A. Yes.

11 Q. When you say IARC would reach a different
12 conclusion now -- strike that.

13 Do you think IARC would reach a different
14 conclusion now? That was the suggestion you are
15 making by saying they may prioritize a review. Are
16 you saying their conclusion would be different?

17 A. I can't speak for their working group. I don't
18 know who would be on it. I don't know what they would
19 decide, but I do know the evidence looks quite
20 different now than it looked 10 years ago.

21 Q. So if you were to suggest to the Court the
22 conclusion would be different, you would be
23 speculating. Right?

24 A. I said I don't know who is going to be on the
25 committee. I don't know what they would state. I do

1 know the evidence has changed, but I can't say how
2 they would vote.

3 Q. My question is different. If you were to say
4 that IARC would change its opinion today, you would be
5 speculating?

6 A. Yes.

7 Q. In order for IARC to move a substance from Group
8 2 B possible to a higher group, IARC would have to
9 rule out chance, bias, and confounding factors, all
10 three. Correct?

11 A. I haven't read the exact criteria for the next
12 level up.

13 Q. You mentioned Health Canada. Let me ask you a
14 few questions about that.

15 You identified 127 documents or other
16 materials as references in your litigation report.
17 Correct?

18 A. Yes.

19 Q. Those materials that you relied on to form the
20 basis of your opinions in this case, right, those are
21 all of the materials. Correct?

22 A. Yes.

23 Q. None of the documents on your reliance list was
24 published by the Food and Drug Administration.

25 Correct?

1 A. I don't recall if I included the letter from
2 them. I don't recall. I would have to look through.

3 Q. None of the documents -- I'll get to that in a
4 second. None of the documents on your reliance list
5 was published by the National Cancer Institute.

6 Correct?

7 A. The National Cancer Institute itself, not a
8 grant that was funded through the National Cancer
9 Institute.

10 Q. Let's take both. How about by NCI itself?

11 A. I don't recall including anything that was from
12 NCI.

13 Q. And branches of NCI --

14 A. Several of the studies I mentioned were funded
15 by NCI.

16 Q. Funded by NCI is one thing, put out by the
17 organization itself is another. Right?

18 A. Yes.

19 Q. Your litigation report identified another 113
20 documents as materials considered, right, in addition
21 to the references?

22 A. I don't know the exact number, but I'll believe
23 you, yes.

24 Q. A few of those documents were led, sent to the
25 FDA. Do you remember that?

1 A. I don't recall.

2 Q. Take a look at Exhibit C 7, your report, page
3 86.

4 A. Is it in Volume 1 or Volume 2?

5 Q. It is in Volume 2. It is your report. It is
6 C-7.

7 A. Okay.

8 Q. Take a look at page 86. All I want to focus you
9 on are items 68 to 70. See those?

10 A. Yes.

11 Q. Those are all letters from the Cancer Prevention
12 Coalition to the FDA; are they not?

13 A. I see two of those, yes.

14 Q. None of those 113 additional materials and data
15 considered were authored by the FDA. Right?

16 A. I don't see it here.

17 Q. None of those documents were published by the
18 NCI. Right?

19 A. None of these -- the numbers you gave me, none
20 say "NCI," no.

21 Q. If you would take a look at Exhibit A 89, I
22 believe, this was not a document you actually relied
23 upon for your opinions in the case. It is one you
24 heard about that talked about migration. Do you
25 recall that?

1 A. Yes.

2 Q. This one is the letter dated April 1, 2014, and
3 I'll direct your attention to the first paragraph on
4 the third page. This is a document that was
5 responsive to the three or four letters that we just
6 looked at on your reference list that were to the FDA.
7 You recall those letters, right?

8 MS. PARFITT: I object. It is on her reliance
9 list, the FDA 2014 letter. Counsel is suggesting she
10 didn't rely on it. That was my understanding of your
11 question.

12 MR. WILLIAMS: That was my understanding. I
13 thought the witness testified it was not on the
14 reliance list. If it is, I'm mistaken. But that
15 doesn't matter for purposes of my question.

16 THE COURT: That's fine.

17 Q. Doctor, I'll ask you this: Whether or not it is
18 on your reliance list, what the letter said in
19 response to those citizens' petitions was paragraph 3:

20 "After careful review and consideration of the
21 information submitted in your petitions, the comments
22 received in response to the petitions, and review of
23 the additional scientific information, this letter is
24 to advise you that FDA is denying your petitions. FDA
25 did not find that the data submitted presented

1 conclusive evidence of a causal association between
2 talc use in the perineal area and ovarian cancer."

3 Did I read that correctly?

4 A. Yes.

5 Q. So you focused the Court on the Health Canada
6 draft study. Correct?

7 A. Yes.

8 Q. You did not point the Court to your review
9 reflecting that government agencies in the United
10 States like the FDA have found that the evidence is
11 insufficient to find a causal association. Right?

12 A. Right. I don't know if the FDA has done a
13 systematic review like Health Canada does. I have not
14 seen a publication of systematic review and causal
15 analysis from the FDA. This is what I've seen, this
16 letter.

17 Q. You don't know one way or the other whether the
18 careful review that is referred to in Exhibit A 89 was
19 a systematic review by your definition?

20 A. They don't reference a systematic review and
21 they don't reference a publication.

22 Q. It is accurate to say that your conclusion here
23 is inconsistent with the conclusions set forth by the
24 FDA in its letter in response to the petition?

25 A. That's correct.

1 Q. Just a couple more things.

2 First I wanted to make sure that --

3 MR. WILLIAMS: Your Honor and counsel, this is
4 the McTiernan report, Exhibit C 7, page 13,
5 description of a confidence interval, forward.

6 Q. I put up a board and I wanted to ask you,
7 Doctor, it says:

8 "If a confidence interval includes the number
9 1.0, then we say the association between the exposure
10 and the disease could be null."

11 Did I read that right?

12 A. Yes.

13 Q. That is your writing in your report. Correct?

14 A. Yes.

15 Q. Now, if a confidence interval in a study were to
16 be exactly 1.0, that would be no association.
17 Correct?

18 A. I don't know what the relative risk is that you
19 are referring to.

20 Q. I misspoke.

21 If the relative risk were reported as 1.0,
22 that would mean no association. Correct?

23 A. Yes.

24 Q. That is to say, if the point estimate were 1.0,
25 that would be no association. True?

1 A. Correct.

2 Q. Okay. If the confidence interval, the range,
3 includes 1.0, that is, it goes above and below 1.0,
4 you cannot say that there is an association. Right?

5 A. What we can say is that the association between
6 exposure and disease could be null. So it could be.
7 That's exactly what I said here, that it could be
8 null.

9 Q. Let me ask you some questions about your -- you
10 mentioned you spoke to Congress, and I just have a
11 couple of questions about that.

12 You indicated you were asked to speak to
13 Congress. Who asked you?

14 A. I believe his name was Mr. Cunningham. He was
15 the Chief of Staff for that subcommittee.

16 Q. Do you know how that particular subcommittee got
17 your name?

18 A. I don't know.

19 Q. Your litigation report in this matter is dated
20 November 16th of last year. Correct?

21 A. If that's what's here, I believe it.

22 Q. A few months later after that you appeared
23 before the subcommittee of Congress. That was on
24 March 12th of this year. Right?

25 A. Yes.

1 Q. You read aloud from a prepared statement that
2 day. Correct?

3 A. Yes.

4 Q. And you were asked to give that testimony -- I
5 think you said this when you spoke that day -- because
6 you had conducted a thorough and systematic review of
7 the science linking use of talcum powder products and
8 the risk of ovarian cancer. Right?

9 A. That's correct.

10 Q. Now, do you know whether or not anybody from
11 Johnson & Johnson was asked to attend that hearing?

12 A. I don't know.

13 MS. PARFITT: Objection, your Honor. I can't
14 imagine how Dr. McTiernan would know if anyone from
15 Johnson & Johnson --

16 THE COURT: I think she already answered it.
17 She said "I don't know."

18 Q. When you appeared that day you were accompanied
19 by several of the plaintiffs' lawyers, is that right,
20 who are in the room today?

21 A. There were several people there. The main
22 person accompanying me was the Vice President for
23 Government Affairs at my institution, Fred Hutchinson.

24 Q. And Ms. Parfitt was there and Ms. O'Dell was
25 there?

1 A. Yes. And several other people in the room.

2 Q. Did you know beforehand plaintiffs' counsel
3 would be attending?

4 A. Yes.

5 Q. Do you know whether plaintiffs' counsel played
6 any role in your being invited to testify?

7 A. I don't know.

8 Q. You don't know one way or at the other?

9 A. I don't know.

10 Q. Did you meet with plaintiffs' counsel in advance
11 of hearing? I don't want to know what you said to
12 them or them to you, but did you meet with them prior
13 to the hearing?

14 A. Yes.

15 Q. Did you travel to the hearing with them?

16 A. No -- travel to the meeting with them?

17 Q. Yes. Did you go over to Congress with them that
18 day?

19 A. Yes.

20 Q. Now, did you share a copy of your written
21 statement to the subcommittee with plaintiffs' counsel
22 before you testified?

23 A. I did, and also to my Vice President of
24 Government Affairs.

25 MS. PARFITT: Your Honor, I object at this

1 point in time. I understand how the substance of Dr.
2 McTiernan's opinions are relevant, but I think we have
3 gone a bit afield as to how she got there. It is
4 clear I was there. Ms. O'Dell was there. I'm just
5 not sure where we are going.

6 MR. WILLIAMS: Counsel raised the issue. I
7 did not.

8 MS. PARFITT: I raised the issue of her
9 appearance before Congress.

10 THE COURT: I understand. I'll permit a few
11 questions.

12 I don't know if you have anything else. I
13 know where you are going with it.

14 MR. WILLIAMS: There is actually a little bit
15 more.

16 THE COURT: Let me hear it.

17 BY MR. WILLIAMS:

18 Q. You told the subcommittee your opinion that
19 perineal talc use is associated with a 22 to
20 31 percent increased risk. Right?

21 A. Yes.

22 Q. You did not talk about cohort studies?

23 A. I didn't talk about specific studies. I talked
24 about totality of evidence.

25 Q. You did not talk about the cohort studies saying

1 there is not an association. True?

2 A. No, I did not.

3 Q. Now, in the written materials that you provided,
4 you mentioned that you had been hired by plaintiffs in
5 litigation.

6 THE COURT: You are referring to written
7 materials she provided to Congress.

8 MR. WILLIAMS: Yes.

9 A. Yes, I disclosed, yes.

10 Q. You disclosed there that you had been hired by
11 plaintiffs in litigation. Right?

12 A. Yes.

13 Q. But in your oral presentation -- which was
14 televised; am I right?

15 A. Yes.

16 Q. In your oral presentation, you did not say that
17 you were hired by plaintiffs' lawyers in litigation,
18 did you?

19 A. I don't recall.

20 Q. In your oral presentation you said that you were
21 there on behalf of consumers. Right?

22 A. I don't have the document right with me.

23 Q. Let's see if we could bring it up.

24 A. Can you tell me what number it is so I could
25 look at the whole thing?

1 Q. It is McTiernan 510 in your book. That would be
2 in book No. 2.

3 My only point is that when you were speaking
4 as opposed to the writing, when you were talking on
5 television, you said as part of this review, I
6 prepared an expert report on behalf of consumers for
7 an ongoing multi-district litigation. Right?

8 A. Oh, so I did disclose. Okay.

9 Q. The word you used was "consumers," not that you
10 were hired by plaintiffs' counsel on behalf of
11 plaintiffs in litigation?

12 A. I didn't use that word, no.

13 Q. You did not indicate in any way that you were
14 there as an expert who was being paid in litigation on
15 behalf of specific plaintiffs, did you?

16 A. I didn't use the word "paid," no.

17 Q. Nor did you use the word "plaintiffs." Right?

18 A. I didn't use the word "plaintiffs," no.

19 Q. And you changed the wording that was contained
20 in your written submission that you used the word
21 "plaintiffs." Right?

22 A. I'm sorry. I can't remember what I said. I
23 just know that I disclosed there. I thought I
24 disclosed here. I don't know what that wording was to
25 compare.

1 MR. WILLIAMS: Thank you, your Honor. No
2 further questions.

3 MS. PARFITT: Do you want to break or go
4 forward?

5 THE COURT: I'm good if you are.

6 Let's take a break.

7 THE DEPUTY CLERK: All rise.

8 (Recess.)

9 (Continued on the next page.)

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1 THE DEPUTY CLERK: All rise.

2 THE COURT: Thank you.

3

4 **ANNE MC TIERNAN**, resumed.

5

6 REDIRECT EXAMINATION

7 BY MS. PARFITT:

8 Q. Good afternoon, Dr. McTiernan. I'm going to try
9 to move as quickly as I can.

10 MS. PARFITT: And I appreciate the Court's
11 indulgence.

12 Q. Dr. McTiernan,, you were asked about your
13 Congressional presentation?

14 A. Yes.

15 Q. And you indicated that I was there and
16 Ms. O'Dell was there. Correct?

17 A. Yes.

18 Q. Were there victims there, too?

19 A. Yes, there were.

20 MR. WILLIAMS: Objection. Not appropriate.

21 THE COURT: They were going to object to the
22 word "victims."

23 Q. Were there "consumers" there?

24 A. Yes.

25 Q. Did the consumers also make statements?

1 A. Yes. There was one that did.

2 Q. Do you recall what the statement was?

3 A. I don't recall his exact statement. He was the
4 son of a woman with ovarian cancer who passed away
5 from the disease.

6 Q. Are you aware whether or not any J&J employees
7 were there?

8 A. I don't know.

9 Q. Now, were you paid by the plaintiffs' counsel
10 here to show up for Congress?

11 A. No.

12 Q. You came on your own volition?

13 A. I came as an independent scientist.

14 Q. Now, throughout the course of the day -- if we
15 could throw up the forest plot.

16 Now, counsel asked you many, many questions
17 about your opinions on consistency. Do you recall
18 those questions by Mr. Williams?

19 A. Yes.

20 Q. Specifically, he talked about the consistency
21 and the role of statistical significance among
22 epidemiological studies. Do you recall that?

23 A. Yes.

24 Q. Do you recall Mr. Williams made a distinction
25 between not what the relative risk was but p-Value or

1 whether something was statistically significant or not
2 statistically significant for purposes of consistency?

3 Do you recall that examination?

4 A. Yes.

5 Q. What I would like to do -- do you know who
6 Kenneth Rothman is?

7 A. Yes.

8 Q. Who is Dr. Rothman?

9 A. He's an epidemiologist who specializes in the
10 methodology of epidemiology and the applications of
11 statistics. I took a course from him in 1977. So I
12 learned his methods early on, and in my Ph.D. program
13 my mentor was a colleague of his. They both trained
14 at Harvard. So I continued to use similar methods
15 after that training.

16 Q. Are you aware Dr. Rothman, along with Sander
17 Greenland and Timothy Lash published A Modern
18 Epidemiology book?

19 A. Yes.

20 Q. Are you familiar with that book?

21 A. Yes.

22 Q. What I would like to do is pull up Chapter 2,
23 page 27, of the Modern Epidemiology, Third Edition, by
24 Doctor Rothman, et al.. At the top of the page it
25 says: Chapter 2, "Causation and Causal Inference."

1 Do you see that?

2 A. Yes.

3 Q. Then there is a section on "Consistency." Do
4 you see that?

5 A. Yes.

6 Q. Why don't you go down to the second full
7 paragraph, and let me ask you a question.

8 Dr. Rothman states:

9 "One mistake in implementing the consistency
10 criterion is so common that it deserves special
11 mention. It is sometimes claimed that a literature or
12 set of results is inconsistent simply because some
13 results are statistically significant and some are
14 not. This sort of evaluation is completely fallacious
15 even if one accepts the use of significance testing
16 methods."

17 Did I read that correctly?

18 A. Yes.

19 Q. Do you agree with Dr. Rothman?

20 A. Yes.

21 Q. Is that opinion consistent with not only that
22 which you shared with the Court today but with Health
23 Canada, the regulatory body for Canada and Congress?

24 A. Yes.

25 Q. Dr. McTiernan, you were asked about IARC's

1 classification of talc back in 2006 when the working
2 group considered it. Do you recall those questions?

3 A. Yes.

4 Q. And you understand, Dr. McTiernan, that IARC's
5 monograph that was published in 2010 was based upon
6 what?

7 A. It was based upon talc without fibrous talc, and
8 it was with the assumption it did not contain
9 asbestos, and it was based on studies up until a
10 couple of years or a year prior to when they did their
11 deliberations.

12 Q. So the evaluation of IARC back in 2006 was
13 literature up until 2006, and that would include
14 literature on biological plausibility. Correct?

15 A. Yes.

16 Q. That would include literature on anything with
17 regard to pathology. Right?

18 A. Yes.

19 Q. That would include literature with regard to
20 mechanistic studies?

21 A. Yes.

22 Q. And that would include the epidemiological
23 literature. Correct?

24 A. Yes.

25 Q. Have you had an opportunity to review IARC's

1 2012 monograph?

2 A. Yes, I have.

3 Q. And how is talc with asbestos classified in IARC
4 2012?

5 A. It is classified as Class 1, the highest level.

6 Q. The highest level of what?

7 A. Carcinogen.

8 Q. Now, you were asked about biological
9 plausibility by Mr. Williams. Does one need a direct
10 and precise evidence of mechanism in order for there
11 to be biological plausibility?

12 A. No.

13 Q. Dr. McTiernan, is asbestos an inflammatory
14 agent?

15 A. Asbestos can cause inflammation, yes.

16 Q. Can fibrous talc cause inflammation?

17 A. Yes.

18 Q. Do both asbestos fibrous talc and heavy metals
19 provide further evidence of a biological plausible
20 explanation that talcum powder products can cause
21 ovarian cancer?

22 A. Yes.

23 Q. You were asked several questions about the
24 Penninkilampi study and the Berge study. Do you
25 recall those?

1 A. Yes.

2 Q. And, specifically, with regard to the issue of
3 dose-response -- you were asked by counsel about some
4 individual source case-control studies. Do you recall
5 that?

6 A. Yes.

7 Q. What I would like to talk to you about are the
8 meta-analyses that were done 2018, just last year.

9 If I understand your testimony correctly, the
10 meta-analysis that were done in 2018 by Berge and by
11 Penninkilampi included the aggregate epidemiological
12 literature on talcum powder products and ovarian
13 cancer. Is that correct?

14 A. That's correct.

15 Q. So those authors looked back. They didn't take
16 a snapshot in 2006 or a snapshot in 2003, but they did
17 a look-back at the epidemiological literature. Is
18 that correct?

19 A. That's correct, and included all of the studies
20 that had been done before that time.

21 Q. That included Dr. Cramer's study back in 1982.
22 Is that correct?

23 A. Yes.

24 Q. Let's talk for a minute on Penninkilampi. A
25 couple of questions. You were asked specifically with

1 regard to the Berge study whether or not there was
2 heterogeneity in the case-control study. Do you
3 recall that question?

4 A. Yes.

5 MS. PARFITT: Cory, would you please bring up
6 Penninkilampi and, specifically, if you would kindly
7 go to page 46.

8 And if you would highlight that first full
9 paragraph.

10 Q. Let me read:

11 "This meta-analysis had several strengths.
12 None of the analyses in this review had statistically
13 significant heterogeneity except for the non-perineal
14 application, which indicates consistency in the
15 direction and magnitude of the effect size between
16 individual studies and strengthening the reliability
17 of the pooled effect sizes."

18 Did I read that correctly?

19 A. Yes.

20 Q. What does that -- what does "heterogeneity"
21 mean? What are they telling us about the consistency
22 of the case-control and cohort studies, because
23 Penninkilampi was case-control and cohort? Correct?

24 A. Yes.

25 Q. What are they telling us?

1 A. From meta-analysis it is common to test whether
2 there is heterogeneity; do the individual studies vary
3 greatly from the overall summary relative risk?

4 First of all, the meta-analyses should do
5 this. It is good methodology. And when they say
6 there is no significant heterogeneity that suggests
7 similar to the points we see on the forest plot, when
8 they test that statistically, things are looking like
9 they track quite well across the studies. The average
10 relative risk reflects what the studies in aggregate
11 are showing.

12 Q. So when we were looking at the case-control
13 cohort studies a little bit earlier, we were looking
14 at this forest plot of case-control and cohort studies
15 and talking about heterogeneity, what is it about that
16 forest plot of case-control and cohort studies in 1982
17 all the way up to 2018? How does that speak to the
18 lack of heterogeneity?

19 A. This is my forest plot, and this shows the
20 studies except for two are to the right. So they are
21 all trending in the positive direction. Looking at
22 the bottom line what these numbers represent.

23 Q. Are you talking about these?

24 A. Yes, it goes from negative .2 up to 4. At the
25 largest relative risk is 4. So you really see what

1 this is referring to. Most of the relative risks are
2 in the same range as what the overall relative risk
3 that the two meta-analyses have found. So it is a
4 very consistent finding, very consistent set of
5 studies.

6 Q. Similarly, you were asked about dose-response.
7 Do you remember that series of questions?

8 A. Yes.

9 Q. What did the Penninkilampi authors find with
10 regard to dose-response?

11 Let's put it up. Let's go to page 45.

12 MS. PARFITT: For the record, it is
13 Exhibit 62.

14 THE COURT: Thank you.

15 Q. Go ahead.

16 A. So they looked both at long-term use and at
17 number of total lifetime applications.

18 MS. PARFITT: Cory, if you could highlight
19 down that last paragraph on the right.

20 Q. Does that help?

21 A. They found a greater risk of ovarian cancer with
22 more than 3600 lifetime applications compared to those
23 with fewer lifetime applications.

24 I would like to point out again the data.
25 That's what I like to look at, the data table.

1 Q. That's Table II.

2 A. In the middle here, where it says "length of
3 use," that whole four lines there, that shows what the
4 numbers "O" were. So less than 3600, the relative
5 risk was 1.32. Over that amount was 1.52. The
6 confidence intervals did not include 1.

7 They also look at long-term use. That was
8 10 years or more, and they found a relative risk of
9 1.29. Also confidence intervals did not include 1.

10 Q. Dr. McTiernan, you were asked about the FDA
11 letter of 2014. Correct?

12 A. Yes.

13 Q. You were asked whether the FDA had made a causal
14 analysis. Is that correct?

15 A. Yes.

16 Q. I believe your response was you did not see they
17 had done a systematic review. Correct?

18 A. Correct.

19 Q. Did Health Canada do a systematic review, and
20 Bradford Hill analysis?

21 A. Yes, they did.

22 Q. Let's see what they had to say about causality.

23 MS. PARFITT: Cory, if you could pull up the
24 Health Canada assessment. Specifically, if you could
25 go to -- okay.

1 Q. Focusing your attention at the next-to-the-last
2 paragraph, it states:

3 "The meta-analysis of the available human
4 studies in the peer review literature indicate a
5 consistent and statistically significant positive
6 association between perineal exposure to talc and
7 ovarian cancer. Further available data are indicative
8 of a causal effect."

9 Did I read that correctly?

10 A. Yes.

11 Q. Do you agree with the opinion of Health Canada
12 with regard to the fact that based upon the
13 meta-analysis, the peer-reviewed literature that not
14 only is there a statistically significant positive
15 association between perineal exposure and talc, but
16 the available data are indicative of a causal effect?

17 A. Yes.

18 Q. Is that consistent with the opinions you have
19 shared with this Court today?

20 A. Yes, it is.

21 Q. Let's go back to Penninkilampi. Page 47. Under
22 "Conclusions."

23 Penninkilampi is a 2018 meta-analysis.
24 Correct?

25 A. Yes.

1 Q. Under "Conclusion":

2 "The results of this review indicate that
3 perineal talc is associated with a 24 percent to
4 39 percent increased risk of ovarian cancer. While
5 the results of case control studies are prone to
6 recall bias especially with intense media attention
7 following commencement of litigation in 2014, the
8 confirmation of an association in cohort studies
9 between perineal talc use and serious invasive ovarian
10 cancer is suggestive of a causal association."

11 Did I read that correctly?

12 A. Yes.

13 Q. Do you agree with the authors of Penninkilampi?

14 A. I do.

15 Q. Are you aware of any more recent meta-analysis
16 since the Berge, Penninkilampi and the Health Canada
17 report?

18 A. Yes. Another meta-analysis was referred to and
19 made available with Health Canada by Taher, et al.

20 Q. Are the conclusions of Health Canada, the
21 Penninkilampi meta-analysis and the Berge
22 meta-analysis all concluding that there is a causal
23 relationship?

24 A. Yes.

25 Q. I should not have included Berge in that. You

1 talk about that?

2 A. The data are remarkably consistent among those
3 three meta-analyses.

4 Q. When you looked at the Berge, regardless of what
5 the narrative is, what is it that you look at?

6 A. I look at the data.

7 Q. And what does the data tell you in the Berge
8 study?

9 A. The data tells me that there is a statistically
10 significant increased risk of ovarian cancer in women
11 that used genital talcum powder products compared to
12 non-users.

13 Q. What does the data tell you in the Berge study
14 with regard to any increased risk in dose-response?

15 A. The Berge also looked at dose-response in models
16 and they found statistically significant association
17 with increased duration and increased frequency of
18 use.

19 Q. Berge was a 2018 meta-analysis?

20 A. Correct.

21 Q. You were asked at the start of Mr. Williams'
22 discussion with you about pleurodesis. Do you recall
23 that?

24 A. Yes.

25 Q. Dr. McTiernan, are you aware of any

1 peer-reviewed literature that indicates whether
2 pleurodesis is associated with adverse effects and it
3 is not advised in patients without malignant pleural
4 effusions?

5 A. Yes. Some clinical groups are recommending that
6 talc not be used for this instance. There was one
7 study that found that small size talc powders were
8 associated with adverse events and --

9 MR. WILLIAMS: I hate to interrupt. I believe
10 this is a new opinion.

11 MS. PARFITT: Your Honor, she was
12 cross-examined by Mr. Williams on the issue of
13 pleurodesis and its health effects. Pleurodesis was a
14 positive thing. It is only fair I be permitted to ask
15 Dr. McTiernan if there are any studies with regard to
16 the adverse effects.

17 MR. WILLIAMS: Counsel raised pleurodesis on
18 direct examination. This is new. The only reason I
19 raised it is they raised it.

20 MS. PARFITT: She's commenting on a study
21 where she's indicating the adverse effects.

22 THE COURT: I have a general answer now and no
23 more beyond that.

24 MS. PARFITT: Thank you.

25 BY MS. PARFITT:

1 Q. Now, if I can direct your attention to the
2 Bradford Hill statement, and, again, that is
3 Exhibit 1.

4 Let me did direct your attention to page 11,
5 interval, under "tests of significance."

6 Dr. McTiernan, referring to the Bradford Hill
7 statement, specifically what Bradford Hill had to say
8 about tests of significance, it read:

9 "No formal activities of significance can
10 answer those questions. Such tests can and should
11 remind us of the effects that the play of chance can
12 create, and they will instruct us in the likely
13 magnitude of those effects. Beyond that, they
14 contribute nothing to the proof of our hypothesis."

15 Did I read that correctly?

16 A. Yes.

17 Q. Do you agree with Sir Bradford Hill?

18 A. I do.

19 Q. I may have misunderstood Mr. Williams' question.
20 I hope I'm not redundant on this. Do you recall you
21 were questioned with regard to your definition of a
22 pooled study? Do you recall that?

23 A. Yes.

24 Q. Let me direct your attention to the Terry study
25 itself.

1 MS. PARFITT: And if you would, Cory, go to
2 page 815.

3 Q. Dr. McTiernan,, how did you characterize or what
4 kind of study design did you characterize the Terry
5 study?

6 A. It is a pooled analysis.

7 Q. What did the authors of the study -- how did
8 they characterize their study?

9 A. As a pooled analysis.

10 Q. They say this pooled analysis of eight case
11 control studies, including 9,859 controls and 8,525
12 ovarian cancer cases?

13 A. Yes.

14 Q. Is that a large study?

15 A. Very large, especially for ovarian cancer which
16 is a rare cancer.

17 Q. What meaningful information can that provide in
18 a study of that size?

19 A. You would have much better ability to determine
20 relative risk, to determine the statistical
21 significance, to look at dose-response, to look at
22 subgroups.

23 Q. The questionnaire for the WHI, the study you
24 were project director for, how did they define talcum
25 powder? Was it all powders? Was it talcum? How it

1 was it defined?

2 A. The question was about powder applied to the
3 private area, and they gave examples of talc,
4 deodorizing powder, or baby powder.

5 Q. Similarly, in the Nurses', the health study,
6 what was the definition of the powder?

7 A. The question was about powder applied to the
8 perineal area, also with an explanation of talc, baby
9 powder, and deodorizing powder.

10 Q. The Sister Study, the third cohort study, how
11 was that question defined?

12 A. Specifically about talc.

13 Q. So two out of the three cohort studies asked
14 generally about powder, talc, cornstarch, deodorizing
15 powder. Is that correct?

16 A. That's correct.

17 Q. What impact would that question have on the
18 relative risk?

19 A. It would reduce it, attenuate it, toward the
20 null, towards 1, because you have less complete
21 information on use of talc. The women who used other
22 powders would be mixed in with talc users.

23 Q. So this error of misclassification would occur?

24 A. Yes.

25 Q. That would attenuate it further towards the

1 null?

2 A. That's right.

3 Q. In other words, the study results would be
4 lower?

5 A. Would be lower than what you would have if they
6 more accurately ascertained talc use.

7 Q. But for that they would have been higher. Is
8 that what you are saying?

9 A. Yes.

10 Q. When I said, misclassification, would it be more
11 correct, it is nondifferential misclassification?

12 A. Yes.

13 MS. PARFITT: Your Honor, I have no further
14 questions.

15 Dr. McTiernan, thank you very much.

16 Your Honor, thank you for your time.

17 MR. WILLIAMS: Your Honor, may I have
18 five-minutes?

19 THE COURT: Yes.

20

21 RECROSS-EXAMINATION

22 BY MR. WILLIAMS:

23 Q. Doctor, I'll be as brief as I can.

24 The first topic you were asked some questions
25 on, the IARC 2012 monograph in redirect examination,

1 let me ask you about that. It is Exhibit A 70 in your
2 book.

3 MR. WILLIAMS: If we would call up page 230,
4 please.

5 Q. I'll direct you to page 230, the left-hand
6 column, Section 1.6 midway down.

7 Do you agree that the 2012 IARC monograph --
8 strike that.

9 Do you agree with the portion of the 2012 IARC
10 monograph that says that "talc containing asbestiform
11 fines is a term that has been used inconsistently in
12 the literature"?

13 A. Can you show me where that is here?

14 Q. The middle of the paragraph.

15 A. I see this.

16 Q. Do you agree with that statement or do you have
17 no knowledge either way?

18 A. I don't have knowledge of that. It sounds like
19 a toxicology question.

20 Q. Not your area?

21 A. Not my area.

22 Q. You did not include in your report IARC's
23 statement that talc containing asbestiform fibers is a
24 term that has been used inconsistently in the
25 literature. True?

1 A. True.

2 Q. And you did not include it in your testimony a
3 few moments ago either, that point?

4 A. True.

5 Q. Do you agree with IARC that the term
6 "asbestiform talc" has erroneously been used for talc
7 products that contain elongated mineral fragments that
8 are not asbestiform?

9 A. I don't have knowledge of that either.

10 Q. No information of either way?

11 A. No.

12 Q. You would defer to people like Mr. Longo for
13 that?

14 A. People with expertise.

15 Q. Do you agree with IARC differences in the use of
16 the same term asbestiform must be considered when
17 evaluating the literature on talc? That is on the
18 same page a little farther down.

19 A. I have no knowledge of that either.

20 Q. And in neither your report nor in the testimony
21 on redirect examination, did you mention any of those
22 things that are also contained in the IARC 2012
23 monograph. Correct?

24 A. Correct.

25 Q. Next topic is Penninkilampi. You were asked

1 about that on redirect examination.

2 MR. WILLIAMS: If we could bring up page 5 of
3 Exhibit A 109.

4 Q. We looked at this earlier. Table 1 on page 5
5 midway down.

6 With respect to the issue of dose-response, do
7 you see the reported odds ratios for the total
8 applications of talc use about halfway down?

9 A. Yes.

10 Q. There are just two categories of data there,
11 less than 36 applications and more than that.
12 Correct?

13 A. Yes.

14 Q. Now, a p-Trend, a p-Value, as you've testified,
15 estimates how likely an observed trend is due to
16 chance. Right?

17 A. It is a little more than that. It is how
18 accurate you would be about saying that -- rejecting
19 there being no trend.

20 Q. Actually, you wrote in your report that a
21 p-Value estimates how likely the observed association
22 is due to chance.

23 A. I know. I was just explaining further.

24 Q. You wrote in your report what I just said.
25 Right?

1 A. I agree.

2 Q. There is no probability or p-Value trend in any
3 of the data you reviewed in Penninkilampi. Is that
4 right?

5 A. Correct. They used confidence intervals
6 instead.

7 Q. There is no p-Value reported anywhere in the
8 study?

9 A. For these data, no. They do have p-Values for
10 heterogeneity and publication bias.

11 Q. With respect to Penninkilampi, which in your
12 report you stated found a dose-response you did so
13 even though the authors themselves did not conclude
14 dose-response. Right?

15 A. I look at the data and, as I mentioned earlier,
16 there were three methods to look at dose-response:
17 one is look at the relative risk with confidence
18 intervals; one is to do p-Value with the unexposed;
19 and one is to do p-Value without the unexposed.

20 Q. In this data, the authors themselves did not
21 report any p-Value at all?

22 A. They did not.

23 Q. Next topic counsel asked you on redirect
24 examination, about a Taher meta-analysis. Do you
25 recall that?

1 A. Yes.

2 Q. Let's take a look at Exhibit A 137.

3 MS. PARFITT: Your Honor, you were very
4 gracious with me, so I do not want to be not gracious
5 myself, but I think we are past our five minutes.

6 MR. WILLIAMS: Forgive me, your Honor, if I
7 may, the Taher study was not part of Dr. McTiernan's
8 articles originally included in her reference list.
9 Counsel just raised it on redirect examination, and so
10 I'm just simply trying.

11 MS. PARFITT: Your Honor, let me be heard on
12 that. At the time of her deposition, we did not have
13 her report. We did not have Health Canada. We
14 supplemented all of that timely. So I don't think
15 that's quite correct.

16 THE COURT: Either way, you've got another
17 couple of minutes. You didn't take up all your time.
18 We're not going to go at this at length, but keep it
19 short, Mr. Williams. It will take us longer to argue
20 the point than give the testimony.

21 BY MR. WILLIAMS:

22 Q. Now, the Taher study is not one of the articles
23 you originally had on your list. Correct?

24 A. Correct.

25 Q. It was made public after your litigation report

1 was submitted as a matter of fact. Right?

2 A. Yes.

3 Q. You are not actually relying on the Taher
4 studies for your opinions in this matter. Is that
5 correct?

6 A. That's correct.

7 Q. The study contains a meta-analysis. Right?

8 A. Yes.

9 Q. And the authors calculated an overall relative
10 risk of 1.28 for their meta-analysis. Right?

11 A. I don't have that table in front of me. Is it
12 in one of these documents?

13 Q. Let's bring up page 29.

14 A. What's the document number?

15 Q. A 137.

16 There is the Section 3.4 meta-analysis. Do
17 you see that reference there, 1.28 with a confidence
18 interval of 1.20 to 1.37?

19 A. Yes.

20 Q. Please turn to the conclusion of the study. It
21 is on page 50, if we could pull that out.

22 In the conclusion it says in that last
23 sentence:

24 "Consistent with previous evaluations the IARC
25 in 2010 and subsequent evaluations by individual

1 investigators, the present comprehensive evaluation of
2 all currently available relevant data indicates that
3 perineal exposure to talc powder is a possible cause
4 of ovarian cancer in humans."

5 Do you see that?

6 A. Yes.

7 Q. That reference specifically states that it is
8 consistent with IARC from 2010. Correct?

9 A. That's what it states.

10 Q. And the IARC definition in 2010 was, as we went
11 through today, that chance, luck, bias, confounding
12 factors could not be ruled out. Correct?

13 A. Yes. But I would note these authors didn't do a
14 full causal analysis. They only did the meta-analysis
15 part.

16 Q. Now, the full causal analysis that you are
17 referring to today that you did --

18 A. Yes.

19 Q. -- includes the biological plausibility that we
20 have gone through with you today. Right?

21 A. Yes.

22 Q. It includes the analysis of consistency that we
23 have gone through with you today. Correct?

24 A. Yes.

25 Q. I take it you disagree with the conclusion of

1 the authors of the Taher study?

2 A. Yes.

3 Q. There are no scientific publications that were
4 available to you during your review in connection with
5 your opinions in this litigation that were not
6 available to the authors of the Taher 2018 study.

7 True?

8 A. I don't know when they did their work.

9 Meta-analysis take a great deal of time. They may
10 take a couple of years. I don't know when they did
11 their reviews and when they did their evaluations.

12 Q. Last thing.

13 On the question of consistency, counsel asked
14 you questions about Penninkilampi and Berge on direct.
15 Do you recall that?

16 A. Yes.

17 Q. The Berge study specifically came to the
18 conclusion -- and this is page 7 of Exhibit A 11:

19 "This analysis provided evidence of
20 heterogeneity of results between the two groups of
21 studies with an association generally detected in
22 case-control studies but not in cohort studies."

23 That's what Berge concluded. Right?

24 A. Yes.

25 Q. That is one of the meta-analyses that you

1 believe was excellent. Right?

2 A. Yes.

3 MR. WILLIAMS: No further questions, your
4 Honor.

5 THE COURT: We're good.

6 MS. PARFITT: We're good.

7 THE COURT: We'll end for the day. Now you
8 are excused.

9 (Witness excused.)

10 (Proceedings adjourned.)

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I N D E X

Proceedings

Page

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Redirect

Recross

Anne McTiernan

By Ms. Parfitt
By Mr. Williams

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C E R T I F I C A T E

PURSUANT TO TITLE 28, U.S.C., SECTION 753, THE
FOLLOWING TRANSCRIPT IS CERTIFIED TO BE AN ACCURATE
TRANSCRIPTION OF MY STENOGRAPHIC NOTES IN THE
ABOVE-ENTITLED MATTER.

S/Vincent Russoniello
Vincent Russoniello, CCR
Certificate No. 675

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